

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

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

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](#)

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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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.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.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.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.levisse

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

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

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

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

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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 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: 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

			Comments
1.	Date of Visit	Not Done _____ //	
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
(b) (6)/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	(b) (6)/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 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 (b) (6)/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

[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
(b) (6)/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

(b) (6)/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 (b) (6)/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 (b) (6)/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
(b) (6)/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

(b) (6)/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.levisse

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
(b) (6)/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
(b) (6)/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
(b) (6)/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

[Back to Form](#)

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
(b) (6)/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

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Laboratory Data Hematology

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

Lab Result

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

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

(b) (6)/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
(b) (6)/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:	//
----	-------	----

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

(b) (6)/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
(b) (6)/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

(b) (6)/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	
----	-------------	--

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 :	(b) (6) /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	[]
----	-----------	-----

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: (b) (6)/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]	

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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.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:	[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: (b) (6)/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]

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

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 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 _____ []
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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

			Comments
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	(b) (6)/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

[Back to Form](#)

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

[Back to Form](#)

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

[Back to Form](#)

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 (b) (6)/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

[Back to Form](#)

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
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.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
(b) (6)/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
(b) (6)/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
(b) (6)/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
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
(b) (6)/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
(b) (6)/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
(b) (6)/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
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
(b) (6)/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
(b) (6)/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
(b) (6)/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
(b) (6)/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
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 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
(b) (6)/2020 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

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.levisse

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.levisse

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 (b) (6)/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
(b) (6)/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

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
(b) (6)/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

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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.levisse

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.levisse

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.

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

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: DEMOGRAPHY - eCRF Audit Trail History

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

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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 use 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: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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

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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Site No: 1128

Subject No: 11281009

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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, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	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: Inclusion Number: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

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Subject No: 11281009

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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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> IN03A00	Initial Entry

I.d

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

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Header Text: c4591001

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Site No: 1128

Subject No: 11281009

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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 Publisher use only): IN04A00	
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Header Text: c4591001

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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

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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Site No: 1128

Subject No: 11281009

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Subject Initials: ---

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			<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)	Data Entry: 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)	Data Entry: 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)	Data Entry: 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)	Data Entry: EX01A00	Initial Entry

2.b

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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Subject No: 11281009

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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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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

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

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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: ---

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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

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Header Text: c4591001

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

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Subject Initials: ---

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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

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

Header Text: c4591001

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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Subject Initials: ---

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			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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			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	
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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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Subject No: 11281009

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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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Subject No: 11281009

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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 13	Initial Entry

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Site No: 1128

Subject No: 11281009

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Subject Initials: ---

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(US & Canada)		(pfe.jdowns)	n Number: Criterion: 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

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.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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Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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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: (Former 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

Site Name: (1128) Ventavia Research Group

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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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			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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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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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: ---

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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: ---

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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[Back to Form](#)**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

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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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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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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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.jafiris06)	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.jafiris06)	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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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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Subject Initials: ---

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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

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

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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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

Visit: V1_DAY1_VAX1_L

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Site No: 1128

Subject No: 11281009

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Site Name: (1128) Ventavia Research Group

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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

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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

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

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

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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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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Subject Initials: ---

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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

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Subject No: 11281009

Generated By: pfe.levissc

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Site Name: (1128) Ventavia Research Group

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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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			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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(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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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.levisse

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[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
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 symp toms present on the last day t he Subject Diary was comple ted?: 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

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

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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)	Data Entry: Symptom:: 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)	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
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 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)	Data Entry: Symptom:: 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 symp</u> NO <u>toms present on the last day</u> <u>the Subject Diary was compl</u> <u>eted?:</u>	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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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[Back to Form](#)**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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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: BHXXNF7	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 (b) (6)/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

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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

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
(b) (6)/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: Ca ndidat e	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: Ca ndidat e	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: Can didate	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: Ans wered	done
Feb-15-2021 14:21:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 8: Op ened	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: Del eted	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
(b) (6)/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 : (b) (6) /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.bougus)	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 (b) (6)/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 (b) (6)2020. Please consider updating the date of visit to (b) (6)2020 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: Opened	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: Reissued: Opened	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: Reissued: Candidate	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: Answered	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: Reissued: Opened	DM: Please verify subject ended study on (b) (6)2020 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
(b) (6)/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 (b) (6) 2020 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
(b) (6)/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

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 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
(b) (6)/2020 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: (b) (6)/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.

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 - eCRF
(b) (6)/2020 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 (b) (6) 2020
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 (b) (6) 2020
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 (b) (6) 2020
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 (b) (6) 2020. Please consider updating the date of assessment to (b) (6) 2020 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 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
(b) (6)/2020 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: (b) (6)/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 (b) (6) 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 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
(b) (6)/2020 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 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
(b) (6)/2020 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 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
(b) (6)/2020 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 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
(b) (6)/2020 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 Not Applicable Present:	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 (b) (6)/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

			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 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
(b) (6)/2020 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 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
(b) (6)/2020 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 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
(b) (6)/2020 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

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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 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
(b) (6)/2020 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.lewissc

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
(b) (6)/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
(b) (6)/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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - (b) (6)/2020 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 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - (b) (6)/2020 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 Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
(b) (6)/2020 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 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
(b) (6)/2020 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 (b) (6)/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 (b) (6)/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

I.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 (b) (6)/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

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 (b) (6)/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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> Not Applicable	Initial Entry
Feb-23-2021 12:02:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u>	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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)	<u>Data Entry:</u> 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
(b) (6)/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 (b) (6)/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.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
(b) (6)/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

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History
(b) (6)/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

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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
(b) (6)/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

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: (b) (6)/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 (b) (6)2020 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: (b) (6)/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

Form Version: 15-Sep-2020 21:53

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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Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

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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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Subject No: 11281009

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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 I nfarction	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

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

				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.jafris06)	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.jafris06)	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.jafris06)	Query 2: Opened	SAE Reason is blank in the AE log. Please provide the source, thanks

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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

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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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Subject No: 11281009

Generated By: pfe.levissc

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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

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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

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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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				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: (b) (6) /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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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)	<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>YES</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</p>	Initial Entry

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			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 If Other, specify: 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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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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Subject No: 11281009

Generated By: pfe.levissc

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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

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

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

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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

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: 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 (b) (6)/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.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

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 (b) (6)/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: (b) (6)/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: (b) (6)/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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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.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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jul/31/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281014

Generated By: pfe.lewissc

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[11281014]
2.	Birth Date:	(b) (6)/1941
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: 11281014

Generated By: pfe.levissc

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: 11281014

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

090177e196ae400f\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: 11281014

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

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
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

090177e196ae400f\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: 11281014

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

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
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

090177e196ae400f\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: 11281014

Generated By: pfe.levissc

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

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
2.1	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

090177e196ae400f\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: 11281014

Generated By: pfe.levisc

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: 11281014

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

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypotension]
	Start Date:	Aug/UNK/2019
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes Type 2]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[elevated cholesterol]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Glaucoma]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae400f\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: 11281014

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.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Muscle Fatigue]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Low Vitamin D]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Arthritis]
	Start Date:	Dec/UNK/2017
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Acid Reflux]
	Start Date:	UNK/UNK/2012
	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: 11281014

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.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vasectomy]
	Start Date:	UNK/UNK/1974
	Ongoing:	NO End Date: UNK/UNK/1974
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Prostate Cancer, malignant]
	Start Date:	UNK/UNK/2008
	Ongoing:	NO End Date: UNK/UNK/2012
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Prostatectomy]
	Start Date:	UNK/UNK/2008
	Ongoing:	NO End Date: UNK/UNK/2008
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tonsillectomy]
	Start Date:	UNK/UNK/1953
	Ongoing:	NO End Date: UNK/UNK/1953

090177e196ae400f\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: 11281014

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.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Appendectomy]
	Start Date:	UNK/UNK/1956
	Ongoing:	NO End Date: UNK/UNK/1956
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tonsillitis]
	Start Date:	UNK/UNK/1953
	Ongoing:	NO End Date: UNK/UNK/1953
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Appendicitis]
	Start Date:	UNK/UNK/1956
	Ongoing:	NO End Date: UNK/UNK/1956

090177e196ae400f\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: 11281014

Generated By: pfe.levisse

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:	[199.4]
3.	Unit:	LB
4.	Height:	[69.5]
5.	Unit:	in
6.	Body Mass Index:	[29.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae400f\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: 11281014

Generated By: pfe.lewissc

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:	[221279]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

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	[BK8CN2]
5.b	Sample ID	[BK8CN3]
5.c	Sample ID	[BN4YDT]
5.d	Sample ID	[BN4YDV]
5.e	Sample ID	[BN4YDW]

090177e196ae400f\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: 11281014

Generated By: pfe.lewissc

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	[BN4YF4]
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090177e196ae400f\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: 11281014

Generated By: pfe.levissc

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 17:51
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae400f\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: 11281014

Generated By: pfe.lewissc

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: 11281014

Generated By: pfe.levissc

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/27/2020
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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED 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

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281014

Generated By: pfe.lewissc

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/27/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.2]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

Generated By: pfe.lewissc

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/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9WFK]
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090177e196ae400f\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: 11281014

Generated By: pfe.levissc

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/27/2020 12:59
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae400f\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: 11281014

Generated By: pfe.levissc

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/24/2020
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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED 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

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

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

eCRF Audit Trail History

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHXN4S]
5.b	Sample ID	[BPR3NG]
5.c	Sample ID	[BPR3VR]

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

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_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

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: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

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: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levissc

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

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

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: 11281014

Subject Initials: ---

Generated By: pfe.levissc

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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

eCRF Audit Trail History

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Sep/24/2020
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: 11281014

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

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: 11281014

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

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: 11281014

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	Right Eye Cataract Removal Surgery	Aug/13/2020 UNK:UNK	NO End Date Time: Aug/13/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	FACIAL LACERATIONS	Aug/28/2020 09:30	NO End Date Time: Aug/28/2020 09:30	Repeating Pages
3.	ADVERSE EVENT	3	Fall	Aug/28/2020 09:30	NO End Date Time: Sep/20/2020 UNK:UNK	Repeating Pages

090177e196ae400f\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: 11281014

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Right Eye Cataract Removal Surgery]
4.	Start Date Time:	Aug/13/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/13/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Cataract]

090177e196ae400f\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: 11281014

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[FACIAL LACERATIONS]
4.	Start Date Time:	Aug/28/2020 09:30
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/28/2020 09:30
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Hypotension]

090177e196ae400f\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: 11281014

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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?	NO
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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fall]
4.	Start Date Time:	Aug/28/2020 09:30
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/20/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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: [Fall]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020337848]

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

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: 11281014

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

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	[]

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.lewissc

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: 11281014

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.	Date:	//

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

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?	

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

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: 11281014

Subject Initials: ---

Generated By: pfe.levissc

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: 11281014

Subject Initials: ---

Generated By: pfe.lewissc

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: 11281014

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?	

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.lewissc

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: 11281014

Subject Initials: ---

Generated By: pfe.lewissc

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

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

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	Dec/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/30/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281014

Generated By: pfe.lewissc

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/30/2020
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.lewissc

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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 - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Dec/30/2020
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

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

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/30/2020
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	[BHXN71]
5.b	Sample ID	[BS7NHM]
5.c	Sample ID	[BS7NCP]

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/30/2020
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	[BHXP1T]
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090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

Form: VACCINATION

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

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/30/2020 13:52
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae400f\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: 11281014

Generated By: pfe.levissc

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

eCRF Audit Trail History

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/22/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPFZN]
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090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281014

Generated By: pfe.lewissc

Form: VACCINATION

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

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/18/2021 15:03
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/25/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281014

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

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

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/25/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281014

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Feb/25/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

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	FOLLOW-UP
2.	Subject Status Date	Sep/24/2020

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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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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: 11281014

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-10-2021 14:55:39 (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.

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-31-2020 09:58:31 (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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Mark Koch	Approved	Mar-10-2021 14:55:39 (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.

Reyna Gomez	N/A	Mar-09-2021 13:26:30 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Mar-08-2021 16:47:00 (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	Feb-25-2021 16:57:38 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

Mark Koch	Approved	Feb-24-2021 13:47:54 (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	Feb-09-2021 12:46:09 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-21-2021 11:46:56 (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	Dec-31-2020 09:58:07 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Dec-28-2020 10:51:33 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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	Dec-21-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Dec-11-2020 10:10:56 (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	Dec-04-2020 09:47:57 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Oct-12-2020 10:52:14 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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.

Mercedes Livingston	N/A	Sep-27-2020 15:48:54 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Sep-22-2020 16:20:44 (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	Sep-22-2020 13:46:18 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Sep-17-2020 18:05:55 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae400f\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: 11281014

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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jul-31-2020 19:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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 19:29:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Jul-31-2020 19:29:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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: 11281014

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Jul-31-2020 19:28:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281014	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jul-31-2020 19:28:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1941	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jul-31-2020 19:29:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jul-31-2020 19:29:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:29:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: WHITE	Initial Entry

090177e196ae400f\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: 11281014

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jul-31-2020 19:30:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Jul/31/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

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
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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: (For Pfizer use only):	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive	Initial Entry

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			, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	
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1.a Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Inclusion Number: 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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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281014**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25***1.b Inclusion Number:***

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Participants who are willing and a ble to comply with all scheduled v isits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

1.b Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: IN02A00	Initial Entry

1.c

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Inclusi 3 on Nu mber:	Initial Entry

Header Text: c4591001

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			<p>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</p> <p>Criterion met?: YES</p> <p>Criterion ID: IN03A00</p> <p>Use only: (For Pfizer use only)</p>	
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Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Inclusion Number:	Initial Entry

Header Text: c4591001

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			<p>Criterion Description: Capable of giving person oral signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol</p> <p>Criterion Met: YES</p> <p>Criterion ID: IN04A00 (For Pfizer use only)</p>	
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Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Exclus 1 ion N umber :	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281014**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 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 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

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Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Exclusion Number: 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	Initial Entry

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2.b Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Exclusion Number:	Initial Entry

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			<p>Criteria 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)</p> <p>Criteria Met?: NO</p> <p>Criteria ID: EX03A00 (For Pfizer use only)</p>	
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Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Exclusion Number: 4 Criterion Description: Receipt of medications intended to prevent COVID-19	Initial Entry

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			Criterion met?: NO	
			Criterion ID : (For Pfizer use only): EX04A00	

2.d Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Exclusion Number:	Initial Entry

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			<p>Criteria on Descriptio n: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</p> <p>Criteria on met?: NO</p> <p>Criteria on ID: (For Pfizer use only): EX08A00</p>	
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Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Immunocompromised individuals with known or suspected immuno deficiency, as determined by histo ry and/or laboratory/physical exa mination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Exclus 10 ion Nu mber:	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Bleeding diathesis or condition as sociated with prolonged bleeding that would, in the opinion of the i nvestigator, contraindicate intram uscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Exclusion Nu 11 mber: Criterion Des Women who are cription: pregnant or breas tfeeding	Initial Entry

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Site Name: (1128) Ventavia Research Group

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Subject Initials: ---

Generated By: pfe.levisse

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			Criterion met NO ?: Criterion ID: EX11A00 (For Pfizer use only):	
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Exclusion Number: 12	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

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			Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: EX12A00 (For Pfizer use only):	
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26	ACV0PFEINFP6000	April Beech	Data Entry:	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-06:00) Central Time (US & Canada)

(pfe.abeech)

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

2.i Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Exclusion Number: 15	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: 11281014

Generated By: pfe.levissc

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

			<p>Criteria Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study</p> <p>Criteria Met?: NO</p> <p>Criteria ID: EX14A01 (For Pfizer use only)</p>	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

2.j Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX14A01	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

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Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

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2.k				
Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 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	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

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2.k Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Exclusion Number:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

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Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

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			Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles Criterion met?: NO Criterion ID: (For Pfizer use only): EX16A01
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2.1 Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: EX16A01	Initial Entry

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Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

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2.m

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 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 ID: NO Criterion ID: EX21A01 Criterion ID: (For Pfizer use only):	Initial Entry

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Header Text: c4591001

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Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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2.m Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 19:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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: 11281014

Generated By: pfe.levissc

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 19:30:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Jul/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-31-2020 19:30:47 (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 19:30:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: COMPLETED	Initial Entry

090177e196ae400f\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: 11281014

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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1.a

Date	Location	User	Value	Reason
Aug-01-2020 08:52:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Te Hypotension rm: Start Date: Aug/UNK/2 019 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:52:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 14:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Closed	Response satisfies query
Aug-31-2020 15:58:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	sorry, unable to add to query on log AE CRF, please add relevant MHx regarding cataracts on new line in MHx CRF. Has been unfrozen for you
Aug-01-2020 08:52:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Hypotension	Initial Entry

1.a Start Date:

090177e196ae400f\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: 11281014

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

Date	Location	User	Value	Reason
Aug-01-2020 08:52:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> Aug/UNK/2019	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:52:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-01-2020 08:53:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number 2 : Medical History Term: Diabetes Type 2 Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

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Subject No: 11281014

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

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I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:53:06 (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 08:53:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Diabetes Type 2	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:53:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2005	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:53:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-01-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: elevated chole sterol Start Date: UNK/UNK/20 10 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11281014

Generated By: pfe.levisse

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> elevated cholesterol	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> UNK/UNK/2010	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-03-2020 09:51:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> Line/MH Number: Medical History Glaucoma Term: Start Date: UNK/UNK/ 2010 Ongoing: YES	Transcription Error
Aug-01-2020 08:53:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number 4	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 11281014

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			r:	
			Medical History	Glacoma
			Term:	
			Start Date:	UNK/UNK/ 2010
			Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1128

Subject No: 11281014

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:53:46 (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
Aug-03-2020 10:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Clo sed	Discrepancy has been closed.
Aug-03-2020 09:51:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Aug-03-2020 09:51:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Glaucoma	Transcription Error
Aug-01-2020 09:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Ope ned	Clarify the term GLACOMA as follows...Should spelling be GLAUCOMA? If so, edit as such. Otherwise, clarify. Thank you.
Aug-01-2020 08:53:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Glacoma	Initial Entry

I.d Start Date:

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 11281014

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Aug-01-2020 08:53:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2010	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:53:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-01-2020 08:54:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 : Medical History Term: Anxiety Start Date: UNK/UNK/1 995 Ongoing: YES	Initial Entry

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Header Text: c4591001

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I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:54:07 (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
Aug-01-2020 08:54:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Anxiety	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:54:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1995	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:54:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-01-2020 08:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 6 : Medical History T Muscle Fatig erm: ue Start Date: UNK/UNK/2 019 Ongoing: YES	Initial Entry

090177e196ae400f\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:** 11281014**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.f Line/MH Number:***

Date	Location	User	Value	Reason
Aug-01-2020 08:54:24 (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
Aug-24-2020 21:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Closed	Response satisfies query
Aug-22-2020 13:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Muscle Fatigue is stable and is not an acute illness per PI assessment
Aug-21-2020 02:28:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Opened	ClinQuery: Muscle Fatigue: The medical history item may be construed as an acute illness that would preclude vaccination per protocol (CCR 8.7.2) . Please review and update item accordingly, or otherwise clarify.
Aug-01-2020 08:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Muscle Fatigue	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2019	Initial Entry

I.f Ongoing:

Header Text: c4591001

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Subject No: 11281014

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Date	Location	User	Value	Reason
Aug-01-2020 08:54:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-01-2020 08:54:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History T Low Vitamin erm: D Start Date: UNK/UNK/2 015 Ongoing: YES	Initial Entry

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Site No: 1128

Subject No: 11281014

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.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:54:47 (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
Aug-01-2020 08:54:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Low Vitamin D	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:54:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2015	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:54:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-01-2020 08:55:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Te Arthritis rm: Start Date: Dec/UNK/20 17 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: 11281014

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.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:55:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 08:55:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Arthritis	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:55:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Dec/UNK/2017	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:55:02 (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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Subject No: 11281014

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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<i>I.i</i>				
Date	Location	User	Value	Reason
Aug-03-2020 09:51:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Line/MH Number: Medical History Term: Start Date: UNK/UNK/ 2012 Ongoing: YES	Transcription Error
Aug-01-2020 08:55:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: UNK/UNK/ 2012 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: 11281014

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.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:55:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-03-2020 10:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-03-2020 09:51:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-03-2020 09:51:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Acid Reflux	Transcription Error
Aug-01-2020 09:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify REFLUX as follows....Are you reporting GASTROESOPHAGEAL REFLUX? VESICOURTERAL REFLUX? HEPATOJUGULAR REFLUX? Other? Please amend the term as appropriate.Thank you.
Aug-01-2020 08:55:18 (UTC-06:00)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Reflux	Initial Entry

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Header Text: c4591001

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Subject No: 11281014

Generated By: pfe.levisse

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Central Time (US & Canada)				
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1.i Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:55:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2012	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:55:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Aug-01-2020 08:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: Vasectomy Start Date: UNK/UNK/1974 Ongoing: NO End Date: UNK/UNK/1974	Initial Entry

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1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 08:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Vasectomy	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1974	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO End Date: UNK/UNK/1974	Initial Entry

1.k

Date	Location	User	Value	Reason
Aug-04-2020 12:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Line/MH Number: 11 Medical History Term: Prostate Cancer, malignant Start Date: UNK/UNK/2008	spoke with subject to receive clarification, cancer was malignant/ts

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Subject No: 11281014

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			Ongoing: NO End Date: UNK/UNK/2012	
Aug-01-2020 08:56:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: Prostate Cancer Start Date: UNK/UNK/2008 Ongoing: NO End Date: UNK/UNK/2012	Initial Entry

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Header Text: c4591001

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Site No: 1128

Subject No: 11281014

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.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:56:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 13:40:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 1: Closed	Response satisfies query.
Aug-04-2020 12:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	spoke with subject to receive clarification, cancer was malignant/ts
Aug-04-2020 12:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Prostate Cancer, malignant	spoke with subject to receive clarification, cancer was malignant/ts
Aug-03-2020 16:06:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 1: Opened	Clinical review: Please specify whether cancer was benign or malignant by updating medex term accordingly.
Aug-01-2020 08:56:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Prostate Cancer	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:56:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2008	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
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Site No: 1128

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Aug-01-2020 08:56:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO End Date: UNK/UNK/2012	Initial Entry
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1.1

Date	Location	User	Value	Reason
Aug-01-2020 08:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: Prostatectomy Start Date: UNK/UNK/2008 Ongoing: NO End Date: UNK/UNK/2008	Initial Entry

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Subject No: 11281014

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1.l Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 08:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Prostectomy	Initial Entry

1.l Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2008	Initial Entry

1.l Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:56:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO End Date: UNK/UNK/2008	Initial Entry

1.m

Date	Location	User	Value	Reason
Aug-01-2020 08:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 13 er: Medical History Tonsillectomy Term: Start Date: UNK/UNK/19 53	Initial Entry

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Subject No: 11281014

Generated By: pfe.levisse

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			Ongoing:	NO	
				End Date:	
				UNK/UNK/ 1953	

Header Text: c4591001

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Subject No: 11281014

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1.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 13:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 1: Closed	Response satisfies query.
Aug-04-2020 12:46:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Aug-03-2020 16:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 1: Opened	Clinical review: Per CRF completion requirements (8.6), when a surgery or interventional procedure is recorded, the condition that led to the surgery/procedure MUST be recorded as a separate entry. Please evaluate and take appropriate action.
Aug-01-2020 08:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Tonsillectomy	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1953	Initial Entry

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Header Text: c4591001

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Subject No: 11281014

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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1.m Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO End Date: UNK/UNK/1953	Initial Entry

1.n

Date	Location	User	Value	Reason
Aug-01-2020 08:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 14 er: Medical History Appendectomy Term: Start Date: UNK/UNK/19 56 Ongoing: NO End Date: UNK/UNK/ 1956	Initial Entry

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

1.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 08:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 13:41:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 1: Closed	Response satisfies query.
Aug-04-2020 12:46:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Aug-03-2020 16:05:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 1: Opened	Clinical review: Per CRF completion requirements (8.6), when a surgery or interventional procedure is recorded, the condition that led to the surgery/procedure MUST be recorded as a separate entry. Please evaluate and take appropriate action.
Aug-01-2020 08:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Appendectomy	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 08:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1956	Initial Entry

090177e196ae400f\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: 11281014

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.n Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 08:57:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO End Date: UNK/UNK/1956	Initial Entry

1.o

Date	Location	User	Value	Reason
Aug-04-2020 12:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 15 Medical History Term: Tonsillitis Start Date: UNK/UNK/1953 Ongoing: NO End Date: UNK/UNK/ 1953	Initial Entry

090177e196ae400f\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: 11281014

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.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 12:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 12:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Tonsillitis	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 12:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: UNK/UNK/1953	Initial Entry

090177e196ae400f\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: 11281014

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.o Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 12:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date: UNK/UNK/1953	Initial Entry

I.p

Date	Location	User	Value	Reason
Aug-04-2020 12:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 16 Medical History Term: Appendicitis Start Date: UNK/UNK/1956 Ongoing: NO End Date: UNK/UNK/ 1956	Initial Entry

090177e196ae400f\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: 11281014

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
Aug-04-2020 12:45:41 (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
Aug-04-2020 12:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Appendicitis	Initial Entry

I.p Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 12:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: UNK/UNK/1956	Initial Entry

I.p Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 12:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date: UNK/UNK/1956	Initial Entry

090177e196ae400f\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: 11281014

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 19:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Jul/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jul-31-2020 19:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 199.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jul-31-2020 19:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Jul-31-2020 19:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 69.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Jul-31-2020 19:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jul-31-2020 19:31:37 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29.0	Initial Entry

090177e196ae400f\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: 11281014

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

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Jul-31-2020 19:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Record Identifier: 1 : Temperature: 97.2 Temperature Unit F : Temperature Loca ORAL CAV tion:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jul-31-2020 19:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jul-31-2020 19:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 97.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jul-31-2020 19:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Jul-31-2020 19:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae400f\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: 11281014

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 19:32:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Jul/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jul-31-2020 19:32:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 221279	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: 11281014

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
Jul-31-2020 19:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-31-2020 19:32:23 (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 08:49:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-31-2020 19:32:23 (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.
Jul-31-2020 19:32:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Jul/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-01-2020 08:49:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BK8CN2	Initial Entry

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-01-2020 08:49:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BK8CN2	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-01-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BK8CN3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-01-2020 08:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BK8CN3	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-01-2020 08:49:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BN4YDT	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-01-2020 08:49:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BN4YDT	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-01-2020 08:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BN4YDV	Initial Entry

090177e196ae400f\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: 11281014

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 08:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BN4YDV	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-01-2020 08:49:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BN4YDW	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-01-2020 08:49:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BN4YDW	Initial Entry

090177e196ae400f\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:** 11281014**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin**

Date	Location	User	Value	Reason
Jul-31-2020 19:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-31-2020 19:33:30 (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 08:50:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-31-2020 19:33:30 (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.
Jul-31-2020 19:33:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Jul/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-01-2020 08:50:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BN4YF4	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-01-2020 08:50:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BN4YF4	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281014

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 19:34:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jul-31-2020 19:34:00 (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 19:34:00 (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 19:34:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Jul/31/2020 17:51	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jul-31-2020 19:34:00 (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 19:34:00 (UTC-06:00) Central	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: LEFT	Initial Entry

090177e196ae400f\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: 11281014

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

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Jul-31-2020 19:34:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jul-31-2020 19:34:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION 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 19:34:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae400f\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: 11281014

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
Sep-13-2020 03:32:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amruta Venkatramani (pfe.venkaa02)	Query 1: Closed	Response satisfies query
Sep-07-2020 09:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Premraj Bhoyar (pfe.bhoyap)	Query 1: Reissued:Opened	eDiary RQ: Per Trial Max Attributes, Vaccination eDiary is needed and REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'Yes'. However eDiary records for Vax 2 is not available. Please verify and clarify in query response.
Sep-04-2020 16:05:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Correct as entered. Patients has been hospitalized.
Sep-03-2020 02:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sagaya Mythili (pfe.mythis)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'Yes' however VAX 2 eDiary records are not available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-01-2020 08:50:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES - REACTOGENICITY E -DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

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-01-2020 10:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Closed	Response satisfies query
Aug-31-2020 14:18:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Query 1: Answered	Visit was completed out of window
Aug-31-2020 03:50:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Opened	PDQ: Date of visit at this visit is out of window (4 day) from Date of visit (31-JUL-20) at V1D1VX1L visit. Please reconcile and update accordingly. Else clarify.
Aug-30-2020 15:10:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/27/2020	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:30**Site No:** 1128**Subject No:** 11281014**Generated By:** pfe.levissc**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - 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. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the last O day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Symptom:: FA TI	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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

			GU E NO	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.b Symptom:

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	<u>Data Entry:</u> 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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	<u>Data Entry:</u> Symptom:: HE AD AC HE NO Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Symptom:

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

2.e

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO	Initial Entry

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Symptom:

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

2.h

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NEW OR WORSE NED JOI NT PAIN	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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: LEFT	Initial Entry

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Injection Site Reaction PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	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-30-2020 15:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1128**Subject No:** 11281014**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-30-2020 15:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/27/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-30-2020 15:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Record Identifier:: 1 Temperature: 97.2 Temperature Unit: F Temperature Locati on:: FOREHE AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-30-2020 15:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Aug-30-2020 15:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: 97.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-30-2020 15:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: F	Initial Entry

2.a Temperature Location:

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-30-2020 15:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	<u>Data Entry:</u> FOREHEAD	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281014**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin**

Date	Location	User	Value	Reason
Aug-30-2020 15:14:55 (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-30-2020 15:14:55 (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-30-2020 15:17:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-30-2020 15:14:55 (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-30-2020 15:14:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: YES Date of Collection: Aug/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-30-2020 15:17:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Sample ID: BP9WFK	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-30-2020 15:17:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: BP9WFK	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281014

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-30-2020 15:17:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-30-2020 15:17:59 (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-30-2020 15:17:59 (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-30-2020 15:17:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/27/2020 12:59	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-30-2020 15:17:59 (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-30-2020 15:17:59 (UTC-06:00) Central	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: LEFT	Initial Entry

090177e196ae400f\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: 11281014

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

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Aug-30-2020 15:17:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-30-2020 15:17:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION 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-30-2020 15:17:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae400f\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: 11281014

Generated By: pfe.levissc

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
Oct-04-2020 20:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Closed	Response satisfies query
Oct-03-2020 11:55:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Query 1: Answered	Requesting medical records release from subject. Once obtained, will request records from the hospital to better update AE/SAE reports
Sep-28-2020 14:00:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Opened	The subject was hospitalized for 26 days; information from discharge summary would be helpful since the specific cause of the fall and long hospitalization is not determined. Please consider an update or fu SAE form. Thank you.
Sep-27-2020 15:48:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Sep/24/2020	Initial Entry

090177e196ae400f\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:** 11281014**Subject Initials:** ---**Generated By:** pfe.lewissc**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
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Symptom:: FE VE R Were fever or systemic s N ymptoms present on the O last day the Subject Diar y was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	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
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Symptom:: FA TI	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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

			GU E	
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO

2.b Symptom:

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	<u>Data Entry:</u> 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
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae400f\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:** 11281014**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**2.c Symptom:**

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	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
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Symptom:: CH IL LS Were fever or systemic s N ymptoms present on the O last day the Subject Diar y was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	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
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NO	Initial Entry

2.e

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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on th e last day the Subject D iary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	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
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on th e last day the Subject D iary was completed?: NO	Initial Entry

090177e196ae400f\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:** 11281014**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**2.f Symptom:**

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	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
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Symptom:: NEW O R WORS ENED M USCLE P AIN Were fever or syste NO mic symptoms pres ent on the last day the Subject Diary was completed?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NEW OR WORSENERED MUS CLE 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
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

2.h

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Symptom:: NEW OR WORSENERD JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (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
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: LEFT	Initial Entry

090177e196ae400f\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: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Injection Site Reaction:: RE DN ES S Were injection site react NO ions present on the last day the Subject Diary w as completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Injection Site Reaction: SW : ELL ING Were injection site reac NO tions present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae400f\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:** 11281014**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	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
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	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
Sep-27-2020 15:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-27-2020 15:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-27-2020 15:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-10-2021 07:39:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 3: Closed	Response satisfies query
Mar-09-2021 13:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Query 3: Answered	Barcode has been added
Mar-09-2021 10:36:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 3: Opened	HOLDS: For V3, the lab received serum sample barcode BPR3VR; however, the barcode has not been recorded. Please review and update as appropriate. Otherwise please clarify.
Oct-06-2020 11:08:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe noig)	Query 2: Closed	Response satisfies query

090177e196ae400f\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, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281014**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Oct-05-2020 21:09:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Query 2: Answered	BPR3NG added
Oct-05-2020 15:38:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 2: Opened	Barcode BPR3NG has been received by the lab for Visit 3. Please review and update or submit SCF.
Sep-27-2020 15:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-27-2020 15:50:05 (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.
Sep-27-2020 15:50:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: YES Date of Collection: Sep/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-27-2020 15:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Sample ID: BHXN4S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-27-2020 15:50:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: BHXN4S	Initial Entry

5.b

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-05-2020 21:09:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Sample ID: BPR3NG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 21:09:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: BPR3NG	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-09-2021 13:26:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BPR3VR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 13:26:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BPR3VR	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levissc

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 16:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sep/24/2020	Changed Information
Oct-04-2020 10:50:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Aug/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-04-2020 10:50:24 (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 10:50:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: COMPLETED	Initial Entry

090177e196ae400f\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: 11281014

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

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Date	Location	User	Value	Reason
Aug-31-2020 14:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Form Deleted	Transcription Error
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

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
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

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
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

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1. Category:

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-01-2020 05:35:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	new query opened on MedHx CRF
Aug-31-2020 14:19:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Query 1: Answered	Changed data per query
Aug-31-2020 12:38:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	Surgical procedures do not need to be listed as AE. If pt has a known hx of cataracts pls add to MHx CRF. If this was a planned surgery then there is no need to report any AE. If pt had worsening of cataract or new dx of cataract, this would be the AE
Aug-30-2020 15:20:31	ACV0PFEINFP6000	Dana Duvak	<u>Data Entry:</u>	Initial Entry

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

(UTC-06:00) Central Time (US & Canada)		(pfe.dduvak)	Right Eye Cataract Removal Surgery	
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4. Start Date Time:

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/13/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO End Date Time: Aug/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Cataract	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

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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, Deleted

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Aug-30-2020 15:20:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Aug-30-2020 15:21:28 (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
Aug-30-2020 15:21:28 (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
Dec-22-2020 07:01:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 2: Closed	Response satisfies query
Dec-21-2020 12:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Closed	Response satisfies query
Dec-21-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Dec-21-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-21-2020 10:42:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: FACIAL LACERATIONS	Changed Information
Dec-18-2020 11:05:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Reissued:Opened	Ae has been unfrozen
Dec-18-2020 06:42:38 (UTC-06:00) Central	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 2: Reissued:Opened	SAE RECON 1: Form is now

090177e196ae400f\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: 11281014 Generated By: pfe.levissc				
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History Form Status: Data Complete, Frozen Site Name: (1128) Ventavia Research Group Subject Initials: --- Generated Time (GMT): 29-Mar-2021 11:25				
Time (US & Canada)				unlock. Please update accordingly.
Dec-17-2020 09:55:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Please unfreeze so that site can make changes
Dec-17-2020 09:47:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	Site would like to amend the name of the event for SAE#2 but cannot make changes. Please unfreeze log line 2 so that site and change the name of the fall to facial lacerations.
Dec-17-2020 07:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON: There are two event terms of fall recorded in the AE log. Please confirm if this non serious AE#2 Fall is a duplicate of AE#3 and update accordingly.
Dec-16-2020 14:18:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Opened	Clinical_ I've closed query on AE#3 and opened in this form so the AE term is revised accordingly. Thank you.
Dec-16-2020 07:24:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Candidate	Clinical_ I've closed query on AE#3 and opened in this form so the AE term is revised accordingly. Thank you.
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Fall	Initial Entry

Header Text: c4591001

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Subject No: 11281014

Generated By: pfe.levisse

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Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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4. Start Date Time:

Date	Location	User	Value	Reason
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/28/2020 09:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO End Date Time: Aug/28/2020 09:30	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-22-2020 16:12:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 2: Closed	Response satisfies query
Sep-22-2020 13:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Sep-22-2020 13:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NOT RELATED If Not Related to study treatm ent(s), this event is due to: OTHER <i>If Other, specify:</i> Hypotension	New Information
Sep-16-2020 12:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 2: Opened	GPDClin: Please clarify if there any medical disorder was identified as the cause of the "fall", e.g., dizziness, dehydration, visual problem, muscle weakness, etc. Or purely due to surface and environmental problems.
Sep-08-2020 08:38:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Sep-04-2020 16:04:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-04-2020 16:04:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NOT RELATED If Not Related to study treatm	New Information

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			ent(s), this event is due to: OTHER <i>If Other, specify:</i> Fall causing facial lacerations requiring prolonged hospitalization	
Sep-02-2020 08:04:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Please update Other Relationship for AE of fall (submit other reason for fall than 'fall')
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Fall	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Header Text: c4591001

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Subject No: 11281014

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Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Aug-30-2020 15:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

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Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-05-2021 18:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 4: Closed	Response satisfies query
Dec-16-2020 07:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 3: Closed	I am closing due to a new query being issued.
Dec-15-2020 16:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 3: Answered	SITE CANNOT MAKE CHANGES TO AE NUMBER 2. PLEASE UNFREEZE LINE 2 SO THAT SITE CAN AMEND TO REFLECT FACIAL LACERATIONS
Dec-15-2020 16:00:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 4: Answered	THE INJURY IS FACIAL LACERATIONS AND IS RECORDED AS AN AE
Dec-11-2020 16:36:51 (UTC-06:00) Central	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 3: Reissued:Open ed	The AE number 2 has been unlocked. Thank you.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281014**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Time (US & Canada)				
Dec-10-2020 18:51:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 4: Opened	ClinQuery: Fall: Is there an injury associated to this event? Per section 8.49.2.3. of CRF completion requirements when a fall results in an injury, both the injury and the fall should be recorded as AEs. Please evaluate and update as appropriate.
Dec-09-2020 10:26:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Query 3: Answered	This AE is correct. AE number 2 needs to be changed to Facial Laceration.
Dec-09-2020 05:32:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 3: Reissued:Open ed	CLINIQUEY: AE unlocked. Kindly amend as appropriate. Thanks.
Dec-08-2020 16:31:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Query 3: Answered	Hypotension is not in subject AEs log and Fall needs to be changed to "Facial Laceration", however AE is locked and cant make change.
Dec-08-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 3: Opened	CLINIQUEY. This event has been recorded correctly. However, per SAE report, there are two additional AEs described, "hypotension" and "facial lacerations", missing in this form. Kindly revise and update AE log accordingly.
Dec-07-2020 04:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	term updated to Fall
Dec-04-2020 09:47:57 (UTC-06:00) Central	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Fall	New Information

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Time (US & Canada)				
Dec-04-2020 08:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	site cannot make changes to eCRF. Please unfreeze and site will change.
Dec-04-2020 05:25:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2020337848, the term in Safety database was updated to 'fall' while retained as 'Facial Lacerations' in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up form.
Oct-30-2020 13:55:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Closed	Thank you.
Oct-29-2020 18:00:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	MR have not been received for the SAE. Subject was contacted via phone, and does not recall if a COVID test was done. Once MR have been received, site can add all information to the SAE FU form.
Oct-26-2020 15:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Reissued:Open ed	The information is not to be recorded on CRF. Please submit FU SAE report, to add in the case narrative. Thank you.
Oct-25-2020 14:16:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	there is not a section on this page to submit if a COVID test was done during SAE. Please clarify where this data should be entered.
Oct-22-2020 12:27:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Opened	COVID testing has not been recorded in the SAE submitted to safety. If test performed = YES, please provide FU form with

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Header Text: c4591001

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Form Status: Data Complete, Frozen

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				results. If NOT test performed or available, please submit FU form as well so it is reflected in the narrative.
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Facial Lacerations	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/28/2020 09:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-22-2020 13:55:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date Time: Sep/20/2020 UNK:UNK	New Information
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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Date	Location	User	Value	Reason
Sep-01-2020 06:18:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Facial Lacerations: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p>	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

			NO	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-03-2020 06:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	resolved
Sep-02-2020 20:08:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	revised form faxed on 01SEP2020 reflects "Not Related" as corrected by PI
Sep-01-2020 06:22:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020337848 ,causality was reported as RELATED in SAE form however, reported as NOT RELATED on AE CRF. Please confirm correct causality. If safety update is required, please submit a follow-up form.
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NOT RELATED If Not Related to study tre atment(s), this event is du e to: OTHER <i>If Other, specify:</i> Fall	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae400f\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: 11281014

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-22-2020 13:55:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 13:54:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Facial Lacerations: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Sep-22-2020 13:54:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RECOVERED/RESOLVED	New Information
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

090177e196ae400f\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: 11281014

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-31-2020 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-01-2020 06:18:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020337848	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-24-2020 09:19:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/22/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

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
Dec-24-2020 09:20:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-24-2020 09:19:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-24-2020 09:19:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

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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I. Date of Visit

Date	Location	User	Value	Reason
Jan-21-2021 16:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Closed	Response satisfies query
Jan-21-2021 10:30:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	done
Jan-19-2021 10:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Reissued:Opened	Please provide the source for this visit in the Complion, thanks
Jan-18-2021 14:36:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	source is not uploaded into complion
Jan-14-2021 13:52:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Please upload the source for this visit into Complion, thanks
Dec-31-2020 09:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Dec/30/2020	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-14-2021 14:06:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Closed	Error
Jan-14-2021 13:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Please upload both the signed ICFs for review, thanks
Dec-31-2020 09:58:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: OBTAINED Date Written Consent Obtained Dec/30/2020	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION
- eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:31**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281014**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-10-2021 06:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Closed	Query closed data has been updated
Feb-09-2021 12:46:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-09-2021 12:46:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/30/2020	Transcription Error
Feb-09-2021 08:19:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	Date of Completion/Discontinuation /Death is reported as 29Dec2020, however subject consented for revaccination on 30Dec2020. Please review and update this date as appropriate. Else clarify.
Dec-31-2020 09:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Dec/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-31-2020 09:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-31-2020 09:58:50 (UTC-06:00) Central	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION
- eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)				
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090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281014**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-31-2020 09:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-31-2020 09:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-31-2020 10:22:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-31-2020 09:59:09 (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.
Dec-31-2020 09:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of Collection: Dec/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-31-2020 10:22:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BHXN71	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-31-2020 10:22:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> BHXN71	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-31-2020 10:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Sample ID: BS7NHM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-31-2020 10:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> BS7NHM	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-31-2020 10:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Sample ID: BS7NCP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-31-2020 10:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> BS7NCP	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281014**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-31-2020 09:59:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-31-2020 09:59:26 (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
Dec-31-2020 10:22:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-31-2020 09:59:26 (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.
Dec-31-2020 09:59:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of Collection: Dec/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-31-2020 10:22:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BHXP1T	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-31-2020 10:22:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BHXP1T	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-31-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-31-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-31-2020 10:00:28 (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
Dec-31-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Dec/30/2020 13:52	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-31-2020 10:00:28 (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
Dec-31-2020 10:00:28 (UTC-06:00) Central	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: LEFT	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: VACCINATION - 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

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Dec-31-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Dec-31-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Dec-31-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-31-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 10:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae400f\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: 11281014

Generated By: pfe.levissc

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
Dec-24-2020 09:20:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/22/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-24-2020 09:20:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

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
Jan-18-2021 14:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Jan/18/2021	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281014**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin**

Date	Location	User	Value	Reason
Jan-18-2021 14:37:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-18-2021 14:37:55 (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
Jan-18-2021 14:38:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:37:55 (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.
Jan-18-2021 14:37:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: YES Date of Collection: Jan/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-18-2021 14:38:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BHPFZN	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 14:38:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BHPFZN	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-18-2021 15:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-18-2021 15:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-18-2021 15:35:56 (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
Jan-18-2021 15:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Jan/18/2021 15:03	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-18-2021 15:35:56 (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
Jan-18-2021 15:35:56 (UTC-06:00) Central	ACV0PFEINFP6000	Linda Langdon	Data Entry: LEFT	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281014

Generated By: pfe.levisse

Form: VACCINATION - 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

Time (US & Canada)		(pfe.llangdon)	
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7. Route:

Date	Location	User	Value	Reason
Jan-18-2021 15:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-18-2021 15:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-18-2021 15:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-18-2021 15:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-18-2021 15:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

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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I. Date of Visit

Date	Location	User	Value	Reason
Mar-01-2021 09:15:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katerina Trpeski (pfe.TRPEsk)	Query 2 : Closed	Response satisfies query
Mar-01-2021 09:04:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rose Madelein (pfe.roseM19)	Query 1 : Closed	Response satisfies query
Mar-01-2021 05:30:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2 : Answered	Original value is correct
Mar-01-2021 02:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 2 : Opened	PDQ: Date of visit V103_MONTH1 is out of window for 3 days from V102_VAX4 DOV or Vaccination date. Please verify and update. Else, confirm in query response appropriately. "[ks66 SDQ=143274]"
Feb-27-2021 08:00:39 (UTC-06:00) Central Time	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1 : Answered	date added

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281014

Generated By: pfe.levissc

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

(US & Canada)				
Feb-26-2021 05:47:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1 : Opened	DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of visit at visit 103.
Feb-25-2021 16:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Feb/25/2021	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281014

Generated By: pfe.lewissc

Form: CONTACT OUTCOME - 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. Contact Type:

Date	Location	User	Value	Reason
Feb-25-2021 16:57:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-25-2021 16:57:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Date of Contact: Feb/25/2021	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281014**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-02-2021 13:48:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 1: Clo sed	Response satisfies query
Mar-02-2021 10:07:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: An swere d	Please review data entered on EOT page for that data, page EOT2 is for visit 103.
Mar-02-2021 07:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7565934;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-27-2021 08:00:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry Feb/2 5/202 1	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-27-2021 08:00:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Feb-27-2021 08:00:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281014

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-04-2020 10:50:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jul-31-2020 19:32:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jul-31-2020 19:30:47 (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
Oct-05-2020 16:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/24/2020	Changed Information
Oct-04-2020 10:50:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/27/2020	Initial Entry
Jul-31-2020 19:32:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/31/2020	Initial Entry
Jul-31-2020 19:30:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/31/2020	Initial Entry

090177e196ae400f\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281014

Subject Initials: ---

Generated By: pfe.levisse

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-17-2020 16:52:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281103

Generated By: pfe.levissc

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/12/2020
----	--------------	--

Header Text: c4591001	Form: DEMOGRAPHY
Visit: COHORT_SELECTION	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 06-Jul-2020 21:55	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281103	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

Demography		
1.	Subject ID	[11281103]
2.	Birth Date:	(b) (6)/1972
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

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/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281103

Generated By: pfe.levissc

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
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Exclusion Criteria Met

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

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

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	Aug/12/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

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:	[muscle spasms]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[restless leg syndrome]
	Start Date:	UNK/UNK/1988
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[low back pain]
	Start Date:	UNK/UNK/1987
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[migraines]
	Start Date:	UNK/UNK/1987
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[shortness of breath]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[bipolar disorder]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

090177e196ae400d\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: 11281103

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.g	Line/MH Number:	[7]	
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[depression]	
	Start Date:	UNK/UNK/2010	
	Ongoing:	YES	
1.h	Line/MH Number:	[8]	
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[seizure disorder]	
	Start Date:	UNK/UNK/2003	
	Ongoing:	YES	
1.i	Line/MH Number:	[9]	
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[seasonal allergies]	
	Start Date:	UNK/UNK/2015	
	Ongoing:	YES	
1.j	Line/MH Number:	[]	Comments
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[]	Comments
	Start Date:	//	Comments
	Ongoing:		Comments
1.k	Line/MH Number:	[11]	
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[hyperlipidemia]	
	Start Date:	UNK/UNK/2019	
	Ongoing:	YES	
1.l	Line/MH Number:	[12]	
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[anxiety]	
	Start Date:	UNK/UNK/2010	
	Ongoing:	YES	

090177e196ae400d\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: 11281103

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.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[osteopenia]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[total hysterectomy]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: UNK/UNK/2002
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[polycystic ovarian disorder]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: UNK/UNK/2002

090177e196ae400d\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: 11281103

Generated By: pfe.levisse

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:	Aug/12/2020
2.	Weight:	[120.2]
3.	Unit:	LB
4.	Height:	[62.0]
5.	Unit:	in
6.	Body Mass Index:	[22.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae400d\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: 11281103
 Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST
 Form Status: Data Complete, Locked, Frozen, Verified
 Site Name: (1128) Ventavia Research Group
 Subject Initials: ---
 Generated Time (GMT): 29-Mar-2021 11:25

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

Lab Urinalysis

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

Lab Result

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

090177e196ae400d\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: 11281103

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 :	Aug/12/2020
2.	Randomization Number:	[47476]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

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: Aug/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BGH7JH]
5.b	Sample ID	[BGH7JJ]
5.c	Sample ID	[BGH7JK]
5.d	Sample ID	[BK8CVK]
5.e	Sample ID	[BK8CVL]

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001	Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:03	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281103	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BGH7S4]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281103

Generated By: pfe.levissc

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/12/2020 14:33
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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001		Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L		Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 06-Jul-2020 21:53		Site Name: (1128) Ventavia Research Group
Site No: 1128		Subject Initials: ---
Subject No: 11281103		Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse		
eCRF Audit Trail History		
Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT

Header Text: c4591001	Form: DATE OF VISIT
Visit: V2_VAX2_L	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: 11281103	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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 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?	YES Ongoing? NO Stop Date: Aug/22/2020
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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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?	YES Ongoing? NO Stop Date: Aug/22/2020

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281103

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:	Sep/1/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

Lab Urinalysis

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

Lab Result

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001	Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Visit: V2_VAX2_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:03	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281103	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
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	[BP9WHV]
-----	-----------	----------

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281103

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:	Sep/1/2020 13:22
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

090177e196ae400d\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: 11281103

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/30/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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 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
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levissc

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: Sep/30/2020
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	[BP5KYV]
5.b	Sample ID	[BPR3PV]
5.c	Sample ID	[BPR3X3]

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001	Form: DATE OF VISIT
Visit: V4_MONTH6_L	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281103	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Feb/23/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPGKK]
5.b	Sample ID	[BS881F]
5.c	Sample ID	[BS887G]

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001	Form: DATE OF VISIT
Visit: V5_MONTH12_L	Form Status: Not Started
Form Version: 22-Apr-2020 21:02	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281103	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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	Oct/14/2020
2.	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
Oct/14/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25**eCRF Audit Trail History****Signs and Symptoms**

1.	Date of Assessment:	Oct/14/2020
2.	Date of First Symptom Started:	Oct/3/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/17/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	YES
4.d	Symptoms:	CHILLS
	Was symptom present?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	YES

Symptoms - Other

5.a	Symptoms - Other Text:	[Nausea]
5.b	Symptoms - Other Text:	[Elevated temperature]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

5.c	Symptoms - Other Text:	[FATIGUE]
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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: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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.	Oct/3/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages
2.	Oct/14/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages
3.	Nov/13/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Oct/3/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[NALT Unknown]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Oct/14/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[NALT Unknown]

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Nov/13/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	INDETERMINATE
8.	Comments/Findings/Details:	[NO RESULTS YIELDED YET]
9.	Trade Name Other, Specify:	[NALT Unknown]

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281103 **Subject Initials:** ---
Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 11:25

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Nov/13/2020
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	[RW90624]
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090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **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: 11281103 **Subject Initials:** ---
Generated By: pfe.lewissc **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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[COVID-19 Tests done on 03OCT2020 and 14OCT2020]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020**Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25**eCRF Audit Trail History****Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES
	Number of Visits or Contacts:	[1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	YES
	Number of Visits or Contacts:	[1]
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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[Form Audit Trail](#)

Hospitalization Details

1.	Hospitalization Category:	Not Applicable _____	Comments
2.	Hospitalization Term:	Not Applicable _____	Comments
3.	Admission Date:	Not Applicable _____ //	Comments
4.	Ongoing?	Not Applicable _____	Comments

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: 11281103

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____	Comments
		[]	
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____	Comments
		[]	
5.	Start Date:	Not Applicable _____	Comments
		//	
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	3

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: 11281103

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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[Form Audit Trail](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

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: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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[eCRF Audit Trail History](#)

Lab Chemistry Details

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

Lab Result

5.a	Sponsor ID:	Unknown _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

5.b	Sponsor ID:	Unknown _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Unknown _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

5.d	Sponsor ID:	Unknown _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Unknown _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

5 f	Sponsor ID:	Unknown _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Unknown _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae400d\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: 11281103

Subject Initials: ---

Generated By: pfe.levisc

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

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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[eCRF Audit Trail History](#)

Laboratory Data Hematology

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

Lab Result

5.a	Sponsor ID:	Unknown _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

5.b	Sponsor ID:	Unknown _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

5.c	Sponsor ID:	Unknown _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

5.d	Sponsor ID:	Unknown _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Unknown _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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

5 f	Sponsor ID:	Unknown _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

5.g	Sponsor ID:	Unknown _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

5.h	Sponsor ID:	Unknown _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments
5.i	Sponsor ID:	Unknown _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

5.j	Sponsor ID:	Unknown _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Unknown _____ []	Comments
	Not Done:	Unknown _____ []	Comments
	LNMT	Unknown _____ Low [] High [] Unit	Comments

090177e196ae400d\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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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

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Vital Signs

1.	Date:	Unknown _____ //	Comments
----	-------	------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Unknown _____ 1	
	Systolic:	Unknown _____ []	Comments
	Diastolic:	Unknown _____ []	Comments
	Respiratory Rate in respirations/minute:	Unknown _____ []	Comments
	Heart Rate in beats/minute:	Unknown _____ []	Comments

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Vital Signs

1.	Date:	Unknown //	Comments
----	-------	---------------	--------------------------

Vital Signs Details

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

Header Text: c4591001		Form: OXYGENATION PARAMETERS		
Visit: POT_COVID_ILL 1		Site Name: (1128) Ventavia Research Group		
Form Version: 06-Jul-2020 21:52		Subject Initials: ---		
Site No: 1128		Generated Time (GMT): 29-Mar-2021 11:25		
Subject No: 11281103				
Generated By: pfe.levisse				
#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Unknown	Unknown	Unknown	Repeating Pages

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Oxygenation Parameters

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

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: 11281103

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.	Unknown	Unknown	Unknown	Unknown	Unknown	Repeating Pages

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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?	Unknown _____ []	Comments
2.	Category:	Unknown _____	Comments
3.	Concomitant Medications Pre-specified:	Unknown _____	Comments
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).	Unknown _____ []	Comments
5.	Start Date:	Unknown _____ //	Comments
6.	Ongoing?	Unknown _____	Comments

090177e196ae400d\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: 11281103 **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.	Unknown	Unknown	Unknown	Unknown	Repeating Pages

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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	Nov/13/2020
2.	Erroneous Visit	ERRONEOUS VISIT

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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.a	Symptoms - Other Text:	Not Applicable	
		[]	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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[Form Audit Trail](#)

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281103 **Subject Initials:** ---
Generated By: pfe.lewissc **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.a	Sample ID	Not Applicable _____ []
-----	-----------	--------------------------------

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

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: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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 _____ []
----	-----------	--------------------------------

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020**Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**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
----	--	----------------	--------------------------

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

Hospitalization Details

1.	Hospitalization Category:	Not Applicable _____	Comments
2.	Hospitalization Term:	Not Applicable _____	Comments
3.	Admission Date:	Not Applicable _____ //	Comments
4.	Ongoing?	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Respiratory Treatment

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

Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020 **Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281103 **Subject Initials:** ---
Generated By: pfe.lewissc **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 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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 2 - Unscheduled Visit on
Nov/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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 2 - Unscheduled Visit on Nov/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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 2 - Unscheduled Visit on
Nov/13/2020

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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 2 - Unscheduled Visit on
Nov/13/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001
Visit: POT_COVID_ILL 2 **Form:** OXYGENATION PARAMETERS
Form Version: 06-Jul-2020 21:52
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281103 **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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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 2 - Unscheduled Visit on Nov/13/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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?	

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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/11/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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: Nov/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BJ6SYG]
5.b	Sample ID	[BJ6ST5]
5.c	Sample ID	[BHXNNJ]

090177e196ae400d\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: 11281103	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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

Unplanned Assessments

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Sep/30/2020
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: 11281103

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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: 11281103

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 Ongoing	Form Instance
1.	ADVERSE EVENT	1	Kidney Stones	Oct/3/2020 UNK: UNK	NO End Date Time: Oct/22/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Severe Hypokalemia	Oct/3/2020 UNK: UNK	NO End Date Time: Oct/22/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Escherichia coli urinary tract infection	Oct/3/2020 UNK: UNK	NO End Date Time: Oct/22/2020 UNK:UNK	Repeating Pages

090177e196ae400d\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: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

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)	[Kidney Stones]	
4.	Start Date Time:	Oct/3/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/22/2020 UNK:UNK	
6.	Toxicity Grade:	2	Comments
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [RENAL CALCULUS]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	YES	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

12.	Was a Non-Drug Treatment given?	NO	Comments
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	[2020405778]	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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)	[Severe Hypokalemia]	
4.	Start Date Time:	Oct/3/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/22/2020 UNK:UNK	
6.	Toxicity Grade:	2	Comments
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [HYPOKALEMIA]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	YES	

090177e196ae400d\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: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

12.	Was a Non-Drug Treatment given?	NO	Comments
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	[2020405778]	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[3]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Escherichia coli urinary tract infection]	
4.	Start Date Time:	Oct/3/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/22/2020 UNK:UNK	
6.	Toxicity Grade:	2	Comments
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [BACTERIAL INFECTION]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	YES	Comments

090177e196ae400d\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: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

12.	Was a Non-Drug Treatment given?	NO	Comments
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	[2020405778]	

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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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	[]

090177e196ae400d\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: 11281103

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

090177e196ae400d\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: 11281103

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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.	Date:	//

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: 11281103

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

090177e196ae400d\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: 11281103

Generated By: pfe.levisse

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?	

090177e196ae400d\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: 11281103

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

090177e196ae400d\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: 11281103

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: c4591001			
Visit: Logs		Form: TRANSFUSIONS	
Form Version: 22-Apr-2020 21:03			
Site No: 1128		Site Name: (1128) Ventavia Research Group	
Subject No: 11281103		Subject Initials: ---	
Generated By: pfe.levisc		Generated Time (GMT): 29-Mar-2021 11:25	
#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae400d\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: 11281103

Generated By: pfe.levisse

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: 11281103

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	Form: VITAL SIGNS - TEMP
Visit: Unplanned Vaccination - Unscheduled	Form Status: Not Started
Form Version: 20-Feb-2021 02:16	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281103	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

Vital Signs	
--------------------	--

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

Vital Signs Details	
----------------------------	--

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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?	

090177e196ae400d\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: 11281103

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: 11281103

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: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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: V201_SURVEIL_CONSENT - Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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: 11281103

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	Jan/19/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

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

[eCRF Audit Trail History](#)

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: c4591001	Form: SUBJECT STATUS
Visit: Subject Status - Unscheduled	Form Status: Data Complete, Verified
Form Version: 22-Apr-2020 21:03	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281103	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/30/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281103

Generated By: pfe.levissc

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: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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 16:53:33 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

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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Item	Date	User	Comment
Form	Aug-12-2020 15:54:05 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

090177e196ae400d\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: 11281103

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - Comments

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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Item	Date	User	Comment
1.j	Sep-18-2020 16:42:59 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	
1.j	Sep-16-2020 13:10:17 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1.j	Sep-16-2020 13:09:30 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1.j	Sep-16-2020 13:08:56 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - Comments

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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Item	Date	User	Comment
1.j	Sep-18-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	
1.j	Sep-16-2020 13:10:17 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - Comments

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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Item	Date	User	Comment
1.j	Sep-18-2020 16:45:35 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	
1.j	Sep-16-2020 13:10:17 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - Comments

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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Item	Date	User	Comment
1.j	Sep-18-2020 16:45:49 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	
1.j	Sep-16-2020 13:10:17 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
Form	Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
1	Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Item	Date	User	Comment
2	Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

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Site Name: (1128) Ventavia Research Group

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Item	Date	User	Comment
3	Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281103

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Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Item	Date	User	Comment
4	Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Item	Date	User	Comment
5	Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

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Item	Date	User	Comment
6.a	Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

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Item	Date	User	Comment
6.a	Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

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Header Text: c4591001

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Subject Initials: ---

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Item	Date	User	Comment
6.a	Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Item	Date	User	Comment
Form	Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281103

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Item	Date	User	Comment
1	Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

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Item	Date	User	Comment
2	Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

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Item	Date	User	Comment
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Header Text: c4591001

Visit: V2_VAX2_L

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
6.a	Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: HOSPITALIZATION DETAILS - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Dec-09-2020 13:18:47 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: HOSPITALIZATION DETAILS - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
1	Dec-09-2020 13:18:47 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: HOSPITALIZATION DETAILS - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2	Dec-09-2020 13:18:47 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: HOSPITALIZATION DETAILS - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

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Item	Date	User	Comment
3	Dec-09-2020 13:18:47 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

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Subject No: 11281103

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Item	Date	User	Comment
4	Dec-09-2020 13:18:47 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Oct-30-2020 18:19:53 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
1	Oct-30-2020 18:19:53 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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Item	Date	User	Comment
2	Oct-30-2020 18:19:53 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Item	Date	User	Comment
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Item	Date	User	Comment
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

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Item	Date	User	Comment
6	Oct-30-2020 18:19:53 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Nov-01-2020 07:12:37 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Per DM Gastroenteritis should not be listed on this page and should only be on the SOD page. <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
1	Nov-01-2020 07:12:37 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Per DM Gastroenteritis should not be listed on this page and should only be on the SOD page. <hr/> Not Applicable

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

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Item	Date	User	Comment
2	Nov-01-2020 07:12:37 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Per DM Gastroenteritis should not be listed on this page and should only be on the SOD page. Not Applicable
2	Nov-01-2020 07:11:23 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	
2	Oct-30-2020 17:48:12 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	This event is Gastro-Intestinal related Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Item	Date	User	Comment
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Item	Date	User	Comment
1	Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. Unknown

Header Text: c4591001

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Header Text: c4591001

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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

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Item	Date	User	Comment
3	Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

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Item	Date	User	Comment
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Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5.j	Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

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Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2.a	Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update.
			Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: VITAL SIGNS - COVID - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

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Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2.a	Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update.
			Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Oct-30-2020 18:24:56 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-30-2020 18:24:56 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
2.a	Oct-30-2020 18:24:56 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Oct-30-2020 18:25:10 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-30-2020 18:25:10 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2	Oct-30-2020 18:25:10 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
3	Oct-30-2020 18:25:10 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
1	Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
2	Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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

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Item	Date	User	Comment
3	Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
4	Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5	Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
6	Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Oct-30-2020 18:26:22 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
1	Oct-30-2020 18:26:22 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2	Oct-30-2020 18:26:22 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
3	Oct-30-2020 18:26:22 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
4	Oct-30-2020 18:26:22 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	medical records not received. once received, site will update. <hr/> Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: DATE OF VISIT - ILLNESS ONSET - 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: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Nov-19-2020 09:58:53 (UTC-06:00) Central Time (US & Canada)	Reyna Gomez (pfe rgomez1)	because symptoms that started 13Nov2020 were within the time line of COVID visit A those symptoms were added to visit A and visit B has been removed per sponsor guidance

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
Form	Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
Form	Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
Form	Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done
Form	Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen

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-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1	Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1	Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1	Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done
1	Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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

Form Status: Data Complete, 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	Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
2	Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
2	Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
2	Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done
2	Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form Version: 10-Oct-2020 16:02

Site No: 1128

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

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Site Name: (1128) Ventavia Research Group

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Item	Date	User	Comment
3	Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
3	Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
3	Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
3	Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done
3	Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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

Form Status: Data Complete, 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	Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.a	Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
4.a	Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.a	Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done
4.a	Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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

Form Status: Data Complete, 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	Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.b	Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
4.b	Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.b	Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done
4.b	Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

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

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Item	Date	User	Comment
4.c	Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.c	Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
4.c	Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.c	Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done
4.c	Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

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Item	Date	User	Comment
4.d	Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.d	Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
4.d	Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.d	Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done
4.d	Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

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Item	Date	User	Comment
4.e	Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.e	Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
4.e	Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.e	Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done
4.e	Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

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4.g	Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.g	Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done
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4.i	Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4.i	Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done
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Item	Date	User	Comment
Form	Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
Form	Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
Form	Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
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Item	Date	User	Comment
1	Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
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1	Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

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Item	Date	User	Comment
2	Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
2	Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
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3	Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
3	Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
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Item	Date	User	Comment
4	Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4	Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
4	Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

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Item	Date	User	Comment
5	Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
5	Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
5	Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

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Item	Date	User	Comment
6	Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
6	Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
6	Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

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Item	Date	User	Comment
7	Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
7	Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
7	Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

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Item	Date	User	Comment
8	Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
8	Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
8	Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
9	Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
9	Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
9	Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

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Item	Date	User	Comment
Form	Dec-17-2020 12:17:09 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	n/a Not Applicable
Form	Dec-17-2020 11:56:32 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	n/a
Form	Dec-16-2020 11:22:51 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	n/a Not Applicable
Form	Dec-13-2020 05:52:25 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	n/a

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Item	Date	User	Comment
1	Dec-17-2020 12:17:09 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	n/a Not Applicable
1	Dec-17-2020 11:56:32 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	n/a
1	Dec-16-2020 11:22:51 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	n/a Not Applicable

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2	Dec-16-2020 11:22:51 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	n/a Not Applicable

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3	Dec-17-2020 11:56:32 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	n/a
3	Dec-16-2020 11:22:51 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	n/a Not Applicable
3	Dec-07-2020 11:47:40 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
3	Dec-07-2020 11:46:40 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	
3	Dec-01-2020 10:17:28 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
3	Nov-25-2020 08:19:23 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	
3	Nov-18-2020 10:04:19 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

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4	Dec-17-2020 11:56:32 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	n/a
4	Dec-16-2020 11:22:51 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	n/a Not Applicable
4	Dec-07-2020 11:47:51 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
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Form	Dec-17-2020 12:17:26 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
Form	Dec-17-2020 11:56:15 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
Form	Dec-07-2020 11:48:12 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
Form	Dec-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

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Item	Date	User	Comment
1	Dec-17-2020 12:17:26 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1	Dec-17-2020 11:56:15 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1	Dec-07-2020 11:48:12 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
1	Dec-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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	Dec-17-2020 12:17:26 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
2	Dec-17-2020 11:56:15 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
2	Dec-07-2020 11:48:12 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
2	Dec-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

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Item	Date	User	Comment
3	Dec-17-2020 12:17:26 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
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3	Dec-07-2020 11:48:12 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
3	Dec-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

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Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

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Site Name: (1128) Ventavia Research Group

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Item	Date	User	Comment
4	Dec-17-2020 12:17:26 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
4	Dec-17-2020 11:56:15 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
4	Dec-07-2020 11:48:12 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
4	Dec-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

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Form: HEALTH CARE UTILIZATION - Comments

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1128

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Subject Initials: ---

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Item	Date	User	Comment
Form	Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
Form	Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
Form	Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
Form	Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form Version: 10-Oct-2020 15:59

Site No: 1128

Subject No: 11281103

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Form: HEALTH CARE UTILIZATION - Comments

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Item	Date	User	Comment
1.a	Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1.a	Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1.a	Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
1.a	Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

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Header Text: c4591001

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Site No: 1128

Subject No: 11281103

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Item	Date	User	Comment
1.b	Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1.b	Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1.b	Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
1.b	Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

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Subject No: 11281103

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Item	Date	User	Comment
1.c	Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1.c	Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1.c	Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
1.c	Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

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Header Text: c4591001

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Subject No: 11281103

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Item	Date	User	Comment
1.d	Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1.d	Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1.d	Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
1.d	Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

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Subject No: 11281103

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Item	Date	User	Comment
1.e	Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1.e	Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1.e	Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
1.e	Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

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Item	Date	User	Comment
1 f	Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1 f	Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1 f	Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
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Item	Date	User	Comment
2	Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
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Item	Date	User	Comment
3	Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
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3	Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: HOSPITALIZATION DETAILS - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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Item	Date	User	Comment
Form	Dec-17-2020 12:21:24 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
Form	Dec-17-2020 11:55:37 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
Form	Dec-07-2020 11:48:36 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
Form	Dec-01-2020 10:16:42 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
Form	Nov-17-2020 17:04:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
Form	Nov-13-2020 14:54:05 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: HOSPITALIZATION DETAILS - Comments

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Form Status: Data Complete, Frozen

Site No: 1128

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Item	Date	User	Comment
1	Dec-17-2020 12:21:24 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
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Item	Date	User	Comment
4	Dec-17-2020 12:21:24 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
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4	Dec-07-2020 11:48:36 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
4	Dec-01-2020 10:16:42 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
4	Nov-17-2020 17:04:14 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
4	Nov-13-2020 14:54:05 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

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Form: ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Dec-17-2020 12:21:43 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
Form	Dec-17-2020 11:55:12 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
Form	Dec-07-2020 11:48:48 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
Form	Dec-01-2020 10:16:23 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form Version: 06-Jul-2020 21:52

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ILLNESS DETAILS - Comments

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Item	Date	User	Comment
1	Dec-17-2020 12:21:43 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1	Dec-17-2020 11:55:12 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1	Dec-07-2020 11:48:48 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
1	Dec-01-2020 10:16:23 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

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Item	Date	User	Comment
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2	Dec-17-2020 11:55:12 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
2	Dec-07-2020 11:48:48 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
2	Dec-01-2020 10:16:23 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

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Item	Date	User	Comment
3	Dec-17-2020 12:21:43 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
3	Dec-17-2020 11:55:12 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
3	Dec-07-2020 11:48:48 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
3	Dec-01-2020 10:16:23 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

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Form Status: Data Complete, Frozen, Not Complete

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Item	Date	User	Comment
6	Oct-30-2020 17:05:52 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
6	Oct-16-2020 19:20:06 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject still in hospital, when released, site will obtain MR <hr/> Unknown

Header Text: c4591001

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Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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Item	Date	User	Comment
12	Oct-30-2020 17:07:39 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
12	Oct-16-2020 19:19:39 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject still in hospital, when released, site will obtain MR <hr/> Unknown

Header Text: c4591001

Visit: Logs - Unscheduled

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Oct-30-2020 17:08:20 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
6	Oct-16-2020 19:23:08 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject still in hospital, when released, site will obtain MR <hr/> Unknown

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
12	Oct-30-2020 17:08:42 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
12	Oct-16-2020 19:23:18 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject still in hospital, when released, site will obtain MR <hr/> Unknown

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Oct-30-2020 17:10:00 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
6	Oct-16-2020 19:24:38 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject still in hospital, when released, site will obtain MR <hr/> Unknown

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen, Not Complete

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	Oct-30-2020 17:10:28 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
11	Oct-16-2020 19:24:53 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject still in hospital, when released, site will obtain MR <hr/> Unknown

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
12	Oct-30-2020 17:10:51 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
12	Oct-16-2020 19:25:04 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject still in hospital, when released, site will obtain MR <hr/> Unknown

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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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 16:53:33 (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.

Thea Sonnier	N/A	Feb-24-2021 16:20:04 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Feb-24-2021 14:00:25 (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.

Linda Langdon	N/A	Feb-23-2021 11:09:55 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-21-2021 11:54:41 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae400d\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:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**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-20-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Dec-28-2020 10:53:27 (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-13-2020 05:52:25 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Dec-11-2020 10:12:20 (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.

Jessica Mendoza	N/A	Dec-03-2020 09:58:54 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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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:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**Affidavit:**

N/A

Mark Koch	Approved	Dec-02-2020 19:37:21 (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.

Reyna Gomez	N/A	Nov-19-2020 09:58:53 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Nov-18-2020 16:37:58 (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	Nov-17-2020 17:39:03 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Nov-17-2020 17:26:28 (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.

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:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Thea Sonnier	N/A	Nov-17-2020 17:24:27 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Mark Koch	Approved	Nov-17-2020 17:22:50 (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.				
Thea Sonnier	N/A	Nov-16-2020 17:01:46 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Mark Koch	Approved	Nov-14-2020 12:28:15 (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.				
Thea Sonnier	N/A	Nov-09-2020 14:38:00 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Mark Koch	Approved	Nov-06-2020 17:36:05 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Header Text: c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**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	Nov-06-2020 15:26:48 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Nov-04-2020 11:05:04 (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	Nov-01-2020 06:36:32 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Oct-31-2020 12:19:45 (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.

Erin McLeod	N/A	Oct-30-2020 17:05:52 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Header Text: c4591001**Visit:** Investigator Signature - Unscheduled**Form Version:** 22-Apr-2020 21:04**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisc**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:**

N/A

Mark Koch	Approved	Oct-23-2020 11:22:33 (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	Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Oct-12-2020 11:12:20 (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.

April Beech	N/A	Sep-30-2020 10:50:47 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Sep-22-2020 16:42:23 (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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281103

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
Aug-12-2020 15:52:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:52:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-12-2020 15:53:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: OBTAINED Date Written Consent Obtained Aug/12/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281103

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
Aug-12-2020 15:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 11281103	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:52:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6)/1972	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-12-2020 15:53:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-12-2020 15:53:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:53:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae400d\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: 11281103

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-12-2020 15:53:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Aug/12/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

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
Aug-12-2020 15:54:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Aug/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-12-2020 15:54:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-12-2020 15:54:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: COMPLETED	Initial Entry

090177e196ae400d\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:** 11281103**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[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Aug-12-2020 15:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term muscle spasms : Start Date: UNK/UNK/2008 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:54:54 (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
Aug-12-2020 15:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: muscle spasms	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2008	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Aug-12-2020 15:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term restless leg syndrom : me	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

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

			Start Date:	UNK/UNK/1988
			Ongoing:	YES

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: restless leg syndrome	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/1988	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:55:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-12-2020 15:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term low back pain : Start Date: UNK/UNK/1987 Ongoing: YES	Initial Entry

090177e196ae400d\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: 11281103

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.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:55:45 (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
Aug-12-2020 15:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: low back pain	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/1987	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-12-2020 15:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term migraines : Start Date: UNK/UNK/198 7 Ongoing: YES	Initial Entry

090177e196ae400d\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: 11281103

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: ---

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I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:56:03 (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
Aug-12-2020 15:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: migraines	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/1987	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-12-2020 15:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: shortness of breath Start Date: UNK/UNK/2018 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: 11281103
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.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:56:30 (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
Aug-20-2020 07:38:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Closed	Response satisfies query
Aug-19-2020 19:49:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	No specific diagnosis available.
Aug-13-2020 09:59:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Opened	Please clarify if a more specific diagnosis was made for this symptom. If yes, please use the diagnosis (underlying medical condition) to replace this symptom term.
Aug-12-2020 15:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: shortness of breath	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2018	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-19-2020 19:46:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Line/MH Number: 6	New Information

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 11281103

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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			Medical History Term: bipolar disorder Start Date: UNK/UNK/2018 Ongoing: YES	
Aug-12-2020 15:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 6 Medical History Term: bipolar Start Date: UNK/UNK/2018 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: 11281103

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: ---

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If Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 07:59:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-19-2020 19:46:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-19-2020 19:46:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: bipolar disorder	New Information
Aug-12-2020 19:14:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify BIPOLAR as follows...The term appears truncated. Are you reporting BIPOLAR DISORDER? BIPOLAR PACEMAKER INSERTION? If so, edit. Otherwise clarify. Thank you.
Aug-12-2020 15:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: bipolar	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2018	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
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Generated By: pfe.levisse

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Aug-12-2020 15:56:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry
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I.g

Date	Location	User	Value	Reason
Aug-12-2020 15:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term depression : Start Date: UNK/UNK/201 0 Ongoing: YES	Initial Entry

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:57:12 (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
Aug-12-2020 15:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: depression	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2010	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-12-2020 15:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8	Initial Entry

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Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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			Medical History Term seizure disorder : Start Date: UNK/UNK/2003 Ongoing: YES	
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I.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 15:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: seizure disorder	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2003	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:57:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Aug-12-2020 15:58:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term seasonal allergie : s Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 11281103

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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I.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 15:58:00 (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
Aug-12-2020 15:58:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: seasonal allergies	Initial Entry

I.i Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 15:58:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2015	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 15:58:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

I.j

Date	Location	User	Value	Reason
Sep-18-2020 16:47:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	will delete line and remove n/a, as the indication was entered in error. (DELETED)
Sep-18-2020 16:45:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	Initial Entry
Sep-18-2020 16:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Line/MH Number: Medical History Term: Start Date:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1128

Subject No: 11281103

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: ---

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			Ongoing: Not Applicable	
Sep-18-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Line/MH Number: Medical History Term: Start Date: Not Applicable Ongoing: Not Applicable	Initial Entry
Sep-18-2020 16:42:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Not Applicable Start Date: Not Applicable Ongoing: Not Applicable	Initial Entry
Sep-16-2020 13:10:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Not Applicable Medical History Term: Not Applicable Start Date: Not Applicable Ongoing: Not Applicable	Initial Entry
Sep-16-2020 13:09:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	Initial Entry
Sep-16-2020 13:08:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Not Applicable Medical History Term: Start Date: Ongoing:	Initial Entry
Sep-16-2020 13:08:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	entered in error-subject denies neuropathy
Aug-12-2020 15:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: neuropathy Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1128

Subject No: 11281103

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

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I,j Line/MH Number:

Date	Location	User	Value	Reason
Sep-18-2020 16:47:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	will delete line and remove n/a, as the indication was entered in error. (DELETED)
Sep-18-2020 16:42:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Sep-16-2020 13:10:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Sep-16-2020 13:09:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Sep-16-2020 13:08:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Sep-16-2020 13:08:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	entered in error-subject denies neuropathy
Aug-12-2020 15:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

I,j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-20-2020 19:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 1: Closed	Response satisfies query
Sep-20-2020 04:14:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey TMS Query (pfe.dubeys27_tmsquery)	Query 2: Closed	Log is deleted.
Sep-18-2020 16:47:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	will delete line and remove n/a, as the indication was entered in error. (DELETED)

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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281103**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

Sep-18-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Sep-18-2020 16:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	will delete line and remove n/a, as the indication was entered in error.
Sep-16-2020 17:14:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Null Term: Verbatim term must not be null/blank.
Sep-16-2020 13:10:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Sep-16-2020 13:08:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	entered in error- subject denies neuropathy
Sep-16-2020 13:08:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	entered in error- subject denies neuropathy
Aug-23-2020 18:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 1: Opened	ClinQuery: Neuropathy: Please add the underlying cause (e.g. diabetes, hypertension etc.) to the reported term; if no underlying cause has been identified please add "idiopathic".
Aug-12-2020 15:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: neuropathy	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281103**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.j Start Date:***

Date	Location	User	Value	Reason
Sep-18-2020 16:47:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	will delete line and remove n/a, as the indication was entered in error. (DELETED)
Sep-18-2020 16:45:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Sep-16-2020 13:10:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Sep-16-2020 13:08:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	entered in error-subject denies neuropathy
Aug-12-2020 15:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2015	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Sep-18-2020 16:47:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	will delete line and remove n/a, as the indication was entered in error. (DELETED)
Sep-18-2020 16:45:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Sep-16-2020 13:10:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Sep-16-2020 13:08:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	entered in error-subject denies neuropathy
Aug-12-2020 15:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

I.k

Date	Location	User	Value	Reason
Aug-12-2020 16:00:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

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

			Medical History Term hyperlipidemia :	
			Start Date: UNK/UNK/2019	
			Ongoing: YES	

I.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:00:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 16:00:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> hyperlipidemia	Initial Entry

I.k Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 16:00:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> UNK/UNK/2019	Initial Entry

I.k Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 16:00:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> YES	Initial Entry

I.l

Date	Location	User	Value	Reason
Aug-12-2020 16:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <u>Line/MH Number:</u> 12 Medical History Term anxiety : Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae400d\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: 11281103

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

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:00:28 (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
Aug-12-2020 16:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: anxiety	Initial Entry

090177e196ae400d\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: 11281103

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.I Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 16:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2010	Initial Entry

I.I Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 16:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

I.m

Date	Location	User	Value	Reason
Aug-12-2020 16:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 Medical History Term osteopenia : Start Date: UNK/UNK/201 5 Ongoing: YES	Initial Entry

090177e196ae400d\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: 11281103

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.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:01:12 (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
Aug-12-2020 16:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: osteopenia	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 16:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2015	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 16:01:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

I.n

Date	Location	User	Value	Reason
Aug-12-2020 16:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History Term: total hysterectomy Start Date: UNK/UNK/2002 Ongoing: NO End Date: UNK/UNK/2002	Initial Entry

090177e196ae400d\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: 11281103

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.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:01:51 (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
Aug-12-2020 16:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: total hysterectomy	Initial Entry

I.n Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 16:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2002	Initial Entry

I.n Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 16:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO End Date: UNK/UNK/2002	Initial Entry

I.o

Date	Location	User	Value	Reason
Aug-12-2020 16:02:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 15 Medical History Term: polycystic ovarian disorder Start Date: UNK/UNK/2002 Ongoing: NO End Date: UNK/UNK/2002	Initial Entry

090177e196ae400d\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: 11281103

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.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:02:52 (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-12-2020 16:02:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: polycystic ovarian disorder	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Aug-12-2020 16:02:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2002	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Aug-12-2020 16:02:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO End Date: UNK/UNK/2002	Initial Entry

090177e196ae400d\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: 11281103
 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
Aug-12-2020 16:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Aug/12/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> 120.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> 62.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	<u>Data Entry:</u> 22.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-12-2020 16:03:30	ACV0PFEINFP6000	Burt Ray	<u>Data Entry:</u>	Initial Entry

090177e196ae400d\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: 11281103

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

(UTC-06:00) Central Time (US & Canada)		(pfe.bray2)	Record Identifier:: 1 Temperature: 97.6 Temperature Unit: F Temperature Location:: FOREHEAD	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> 97.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> FOREHEAD	Initial Entry

090177e196ae400d\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:** 11281103**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:**

Date	Location	User	Value	Reason
Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

			Not Done::	Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-12-2020 16:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae400d\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: 11281103

Generated By: pfe.levisse

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
Aug-12-2020 16:04:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Aug/12/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-12-2020 16:04:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> 47476	Initial Entry

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
 Form Version: 22-Apr-2020 21:03
 Site No: 1128
 Subject No: 11281103
 Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Aug-13-2020 08:44:39 (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-13-2020 08:44:39 (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-13-2020 08:46:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 08:44:39 (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-13-2020 08:44:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES Date of Collection: Aug/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-13-2020 08:46:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sample ID: BGH7JH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 08:46:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: BGH7JH	Initial Entry

090177e196ae400d\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
 Site No: 1128
 Subject No: 11281103
 Generated By: pfe.levisse

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

5.b

Date	Location	User	Value	Reason
Aug-13-2020 08:47:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Sample ID: BGH7JJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 08:47:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> BGH7JJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-13-2020 08:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Sample ID: BGH7JK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 08:47:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> BGH7JK	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-13-2020 08:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Sample ID: BK8CVK	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 08:48:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> BK8CVK	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-13-2020 08:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Sample ID: BK8CVL	Initial Entry

090177e196ae400d\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: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

5.e Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 08:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: BK8CVL	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1128
Subject No: 11281103
Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Aug-13-2020 08:49:30 (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-13-2020 08:49:30 (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
Sep-12-2020 12:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (pfe.dubeys27)	Query 2: Closed	Will check in LIMS report for update. If required, re-query will be raised.
Sep-11-2020 08:07:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Query 2: Answered	Per Sample Control Form sample BGH7S4 was collected at Visit 1 on 12AUG2020 for subject 11281103.
Sep-08-2020 02:56:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (pfe.dubeys27)	Query 2: Opened	LIMS Query: Sample ID - BP9WHV is missing. Please check if current Sample ID can be corrected, else clarify or confirm if SCF is submitted.
Aug-13-2020 08:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 08:49:30 (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-13-2020 08:49:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES Date of Collection:	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

			Aug/12/2020	
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5.a

Date	Location	User	Value	Reason
Aug-13-2020 08:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sample ID: BGH7S4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 08:49:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: BGH7S4	Initial Entry

090177e196ae400d\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: 11281103

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-12-2020 16:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-12-2020 16:05:43 (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-12-2020 16:05:43 (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-12-2020 16:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Aug/12/2020 14:33	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-12-2020 16:05:43 (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-12-2020 16:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-12-2020 16:05:43	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae400d\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: 11281103

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

(UTC-06:00) Central Time (US & Canada)		(autocalc)	INTRAMUSCULAR	
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-12-2020 16:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 16:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

090177e196ae400d\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: 11281103

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-12-2020 16:05:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES - REACTOGENICITY E-DIARY C OLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

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-02-2020 11:55:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/1/2020	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:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**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
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	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
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	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
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Symptom:: FAT IGU E Were fever or systemic symptoms present on the last day the Subjec t Diary was completed?: 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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> 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
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-18-2020 17:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> Symptom:: HEADAC HE Were fever or systemic sy YES mptoms present on the last Ongoing day the Subject Diary was ? completed?: NO Stop Date: Aug /22/ 202 0	Transcription Error
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Symptom:: HEA DAC HE Were fever or systemic sympto NO ms present on the last day the S ubject Diary was completed?:	Initial Entry

090177e196ae400d\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: 11281103
 Subject Initials: ---
 Generated By: pfe.levisse
 Generated Time (GMT): 29-Mar-2021 11:25

2.c Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> 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
Sep-19-2020 06:57:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoia)	Query 1: Closed	Response satisfies query
Sep-18-2020 17:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> YES Ongoing? NO Stop Date: Aug/22/2020	Transcription Error
Sep-18-2020 16:54:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	Per review of Trial Max system, DOV 01SEP2020, there were no reported symptom, data entered correctly.
Sep-03-2020 11:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Isaac Arasavalli (pfe.arasai)	Query 1: Opened	e-Diary: Per eDiary records, HEADACHE is reported on Last day (Day 7) however the last day in inform is entered as 'No' for the same. Please verify and update. Else, clarify. Thanks.
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> <u>Symptom::</u> CH ILL S	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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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.d Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<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
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> <u>Symptom::</u> VO MITI NG Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<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
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u>	Initial Entry

090177e196ae400d\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: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)			Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	
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2.f Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	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
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Symptom:: NEW OR WORSENERED MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NEW OR WORSENERED 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
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

090177e196ae400d\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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

2.h

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Symptom:: NEW OR WORSENE D JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (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
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Injection Site Reaction:: REDNES	Initial Entry

090177e196ae400d\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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

			Were injection site reactions present on the last day the Subject Diary was completed?:	NO
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLIN G Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-18-2020 17:22:03 (UTC-06:00) Central Time	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u>	Transcription Error

090177e196ae400d\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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)			Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Aug/22/2020	
Sep-18-2020 17:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Sep/22/2020	Transcription Error
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae400d\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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	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
Sep-19-2020 06:56:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoi)	Query 1: Closed	Response satisfies query
Sep-18-2020 17:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-18-2020 17:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Ongoing? NO Stop Date: Aug/22/2020	Transcription Error
Sep-18-2020 17:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Injection Site Reaction Stop Date is a future date relative to when it was entered. Please correct.
Sep-18-2020 17:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Ongoing? NO Stop Date: Sep/22/2020	Transcription Error
Sep-18-2020 16:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	Per review of Trial Max system, DOV 01SEP2020, there were no reported symptom, data entered correctly.
Sep-03-2020 11:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Isaac Arasavalli (pfe.arasai)	Query 1: Opened	e-Diary: Per eDiary records, PAIN AT INJECTION SITE is

090177e196ae400d\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: 11281103
Subject Initials: ---
Generated By: pfe.lewissc
Generated Time (GMT): 29-Mar-2021 11:25

				reported on Last day (Day 7) however the last day in inform is entered as 'No' for the same. Please verify and update. Else, clarify. Thanks.
Sep-02-2020 11:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**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
Sep-02-2020 11:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/1/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-02-2020 11:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Record Identifier:: 1 Temperature: 97.6 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry
Sep-02-2020 11:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Record Identifier:: 1 Temperature: 97.6 Temperature Unit: Temperature Location:: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-02-2020 11:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-02-2020 11:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 97.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-02-2020 11:57:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	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: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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

Sep-02-2020 11:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> FOREHEAD	Initial Entry
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090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:**

Date	Location	User	Value	Reason
Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

			Not Done::	Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-02-2020 11:57:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

090177e196ae400d\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:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-11-2020 09:04:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-11-2020 09:04:50 (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
Sep-11-2020 09:05:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 09:04:50 (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.
Sep-11-2020 09:04:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-11-2020 09:05:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BP9WHV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 09:05:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BP9WHV	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281103

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
Sep-02-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-02-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-02-2020 11:58:50 (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
Sep-02-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/1/2020 13:22	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-02-2020 11:58:50 (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
Sep-02-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-02-2020 11:58:50	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae400d\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: 11281103

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

(UTC-06:00) Central Time
(US & Canada)

(autocalc)

INTRAMUSCULAR

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-02-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 11:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

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
Oct-17-2020 06:47:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharat Nair (pfe.nairs51)	Query 1: Closed	Response satisfies query
Oct-16-2020 18:07:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	subject was contacted on 14OCT2020, per PI subject is to seek treatment from PCP immediately. Event added to EDC.
Oct-16-2020 07:26:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharat Nair (pfe.nairs51)	Query 1: Opened	Illness eduary: As per Illness eduary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 09OCT2020. But corresponding COVID Illness visit not reported. Please clarify.
Sep-30-2020 10:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sep/30/2020	Initial Entry

090177e196ae400d\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: 11281103 **Subject Initials:** ---
Generated By: pfe.levisse **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
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subjec t Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: FAT IGU E Were fever or systemic symptoms present on the last day the Subjec t Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
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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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: CH ILL S	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: 11281103
Subject Initials: ---
Generated By: pfe.levisse
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.d Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: VO MITI NG Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry:	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: 11281103 Subject Initials: ---
 Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 11:25

(US & Canada)			Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO
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2.f Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: NEW OR WORSENE D MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NEW OR WORSENE D 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
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
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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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

2.h

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: NEW OR WORSENE D JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (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
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Injection Site Reaction:: REDNESS	Initial Entry

090177e196ae400d\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: 11281103 Subject Initials: ---
 Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 11:25

			Were injection site reactions present on the last day the Subject Diary was completed?:	
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5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLIN G Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u>	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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)			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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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> 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
Sep-30-2020 10:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae400d\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:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-30-2020 10:51:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-30-2020 10:51:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-30-2020 12:26:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 10:51:28 (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.
Sep-30-2020 10:51:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-30-2020 12:26:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BP5KYV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 12:26:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BP5KYV	Initial Entry

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: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

5.b

Date	Location	User	Value	Reason
Sep-30-2020 12:27:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BPR3PV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 12:27:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BPR3PV	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-30-2020 12:27:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BPR3X3	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 12:27:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BPR3X3	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

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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I. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 11:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Feb/23/2021	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:** 11281103**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-23-2021 12:15:10 (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 12:15:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-23-2021 12:15:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 12:15:10 (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.
Feb-23-2021 12:15:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: YES Date of Collection: Feb/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-23-2021 12:15:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BHPGKK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 12:15:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BHPGKK	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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

5.b

Date	Location	User	Value	Reason
Feb-23-2021 12:15:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Sample ID: BS881F	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 12:15:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: BS881F	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-23-2021 12:16:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Sample ID: BS887G	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 12:16:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: BS887G	Initial Entry

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Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281103 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-07-2020 10:07:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe.riddlj)	Query 3: Closed	Other queries currently open to site asking to update these forms
Nov-05-2020 09:17:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 3: Reissued:Candidate	site has not received records, once received, this will be added to EDC and updates faxed.
Nov-04-2020 17:55:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 3: Answered	site will update once records received
Nov-04-2020 00:50:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Usha Ogirala (pfe.ogirau)	Query 3: Reissued:Opened	DM: Please update the data requested in previous query once data is available, until then kindly keep this query in open status. Thank you.
Nov-03-2020 16:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 3: Answered	site will update once records received
Nov-03-2020 15:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 3: Reissued:Opened	Please update once data is available. Thank you.
Nov-03-2020 08:16:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Nov-02-2020 20:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 3: Answered	site has not received records, once received, this will be added to EDC and updates faxed.
Nov-02-2020 20:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	neither self swab or office swab was done as subject was in the hospital and had NAAT test done.
Nov-02-2020 05:33:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 3: Opened	DM: Per comment, please update LOCAL LABORATORY DATA - REPEATING

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

				CHEMISTRY, LOCAL LABORATORY DATA - REPEATING HEMATOLOGY, IMAGING, VITAL SIGNS - COVID, OXYGENATION PARAMETERS and VITAL SIGNS - PULSE OX ROOM AIR forms once data is available.
Nov-02-2020 01:27:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Opened	DM: Please review per SOD form, subject has reported symptoms hence at least one of swab collection is expected. Kindly verify and confirm the data.
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-30-2020 17:45:28 (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.
Oct-30-2020 17:45:28 (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.
Oct-30-2020 17:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Oct/14/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-30-2020 17:45:28 (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 Oct/14/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.lewissc**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Oct/14/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Oct/3/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 03:45:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloi (pfe.moloim)	Query 2: Closed	Response satisfies query
Feb-23-2021 12:29:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO Date of Last Symptom Resolved: Nov/17/2020	New Information
Feb-23-2021 12:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-23-2021 12:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO Date of Last Symptom Resolved: Oct/22/2020	New Information
Feb-14-2021 23:06:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Bembem Takhellambam (pfe.takheb)	Query 2: Opened	Please confirm the symptoms are still ongoing for this COVID illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else clarify. Thanks
Nov-17-2020 17:24:49	ACV0PFEINFP6000	Thea Sonnier	Data Entry:	New Information

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)		(pfe.tsonnier)	YES	
Nov-07-2020 23:44:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Closed	Response satisfies query
Nov-06-2020 15:26:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-06-2020 15:26:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO Date of Last Symptom Resolved: Oct/17/2020	New Information
Nov-05-2020 22:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Per source, ended on 17 OCT 2020. Please verify and update, thanks
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Pre NO sent:	Initial Entry
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4.b Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptom NEW OR INCREASED SH s: ORTNESS OF BREATH Symptom YES Present:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-17-2020 17:24:27 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

(US & Canada)			Symptoms: CHILLS Symptom Present: YES	
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-17-2020 17:24:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Changed Information
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-17-2020 17:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P YES resent:	New Information
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P NO resent:	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**4.e Symptoms:**

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-17-2020 17:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	New Information
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

			Symptom P YES resent:	
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4.g Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: DIARRHEA Symptom Present: YES	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: VOMITING Symptom Present: YES	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**4.i Symptoms:**

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-30-2020 17:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-30-2020 17:56:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms - Other: Nausea	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-30-2020 17:56:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Nausea	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-01-2020 12:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms - Other: Elevated temperature	updated per DM
Oct-30-2020 17:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms - Other: Subjective Fever	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**5.b Symptoms - Other Text:**

Date	Location	User	Value	Reason
Nov-01-2020 14:19:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Nov-01-2020 12:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per DM
Nov-01-2020 12:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Elevated temperature	updated per DM
Nov-01-2020 11:12:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Opened	Clinical Query: Per response, please consider updating to elevated temperature.
Nov-01-2020 10:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	fever did not get above 100.0
Nov-01-2020 10:32:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Opened	Clinical Query: Per protocol Section 8.2.2.4, fever is defined as 100.4F. Please update.
Nov-01-2020 06:38:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	fever, per protocol and PI, is 104, the subjects temperature did not reach this. Per PI these events should be listed as subjective fever and not fever.
Oct-31-2020 17:36:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clinical Query: Does this refer to fever? If so, please record under 4a.
Oct-30-2020 17:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Subjective Fever	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-17-2020 17:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms - Other: FATIGUE	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Nov-17-2020 17:25:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms - Other:	New Information
Nov-09-2020 14:38:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms - Other:	Transcription Error (DELETED)
Nov-02-2020 21:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms - Other:	Transcription Error
Nov-02-2020 20:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms - Other: Diarrhea	updated per DM
Nov-01-2020 06:36:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms - Other: Gastroenteritis	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-17-2020 17:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: FATIGUE	Initial Entry
Nov-17-2020 17:25:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	New Information
Nov-10-2020 10:40:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharreda Cornes (pfe.cornes09)	Query 2: Closed	Response satisfies query
Nov-09-2020 14:38:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Transcription Error (DELETED)
Nov-09-2020 14:37:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	gastroenteritis entry is removed
Nov-05-2020 23:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Opened	Please complete. Per source Gastroenteritis but the symptom 'Diarrhea' already mentioned above.
Nov-02-2020 21:34:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Nov-02-2020 21:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-02-2020 21:01:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Transcription Error
Nov-02-2020 20:42:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Opened	Clinical Query: Diarrhea is already recorded under 4h. Please remove.
Nov-02-2020 20:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per DM
Nov-02-2020 20:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Diarrhea	updated per DM

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Nov-02-2020 17:14:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clinical Query: Please enter symptoms of gastroenteritis instead of diagnosis. Diagnosis of gastroenteritis is already recorded on ILL POTEN CRF.
Nov-01-2020 06:36:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Gastroenteritis	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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Date	Location	User	Value	Reason
Oct-30-2020 18:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Oct-30-2020 18:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Nov-17-2020 17:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Created	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Oct-30-2020 18:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Oct/3/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-30-2020 18:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-30-2020 18:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-30-2020 18:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME C ORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-30-2020 18:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-30-2020 18:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Nov-09-2020 15:20:38	ACV0PFEINFP6000	Syed Jafri	Query 1: Closed	Response satisfies

Header Text: c4591001 Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form Version: 06-Jul-2020 21:54 Site No: 1128 Subject No: 11281103 Generated By: pfe.levisse				
		Form: MICROBIOLOGY SPECIMEN - 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		
(UTC-06:00) Central Time (US & Canada)		(pfe.jafri06)		query
Nov-09-2020 14:38:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	source updated
Nov-05-2020 23:01:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Please provide the source (Negative is not checked in the source), thanks
Oct-30-2020 18:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEGATIVE	Initial Entry
9. Trade Name Other, Specify:				
Date	Location	User	Value	Reason
Nov-09-2020 15:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Closed	Response satisfies query
Nov-09-2020 14:40:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	source updated
Nov-05-2020 23:03:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Opened	Please provide the source (NALT UNK is not in the source), thanks
Nov-02-2020 20:40:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Nov-02-2020 20:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	both trade name and lab are not known
Nov-01-2020 14:21:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Opened	Clinical Query: If test was conducted at 'CLIA-certified lab', please enter that instead of NALT Unknown.
Nov-01-2020 12:45:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	test conducted at CLIA-certified lab or ISO 15189 accredited lab.
Nov-01-2020 12:45:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NALT Unknown	test conducted at CLIA-certified lab or ISO 15189 accredited

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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				lab.
Nov-01-2020 11:14:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clinical Query: Per CRF CRs 8.31.7, please provide manufacturer and test kit name. If not available, please indicate if test conducted at 'CLIA-certified lab' or 'ISO 15189 accredited lab.' If both trade name and lab are not known, enter 'NALT Unknown.'
Oct-30-2020 18:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Oct-30-2020 18:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Oct/14/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-30-2020 18:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-30-2020 18:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-30-2020 18:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME C ORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-30-2020 18:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-30-2020 18:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Oct-30-2020 18:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEGATIVE	Initial Entry
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9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-09-2020 15:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Closed	Response satisfies query
Nov-09-2020 14:41:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	source is updated
Nov-05-2020 23:03:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Opened	Please provide the source (NALT UNK is not in the source), thanks
Nov-02-2020 20:40:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Nov-02-2020 20:18:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	both trade name and lab are not known
Nov-01-2020 14:21:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Opened	Clinical Query: If test was conducted at 'CLIA-certified lab', please enter that instead of NALT Unknown.
Nov-01-2020 12:46:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	test conducted at CLIA-certified lab or ISO 15189 accredited lab
Nov-01-2020 12:46:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NALT Unknown	test conducted at CLIA-certified lab or ISO 15189 accredited lab
Nov-01-2020 11:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clinical Query: Per CRF CRs 8.31.7, please provide manufacturer and test kit name. If not available, please indicate if test conducted at 'CLIA-certified lab' or 'ISO 15189 accredited lab.' If

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
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Subject Initials: ---

Generated By: pfe.lewissc

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				both trade name and lab are not known, enter 'NALT Unknown.'
Oct-30-2020 18:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Nov-17-2020 17:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/13/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-17-2020 17:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-17-2020 17:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-17-2020 17:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME C ORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-17-2020 17:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-17-2020 17:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Dec-02-2020 10:41:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Dec-02-2020 08:04:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	results are unknown
Dec-02-2020 00:00:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 1: Reissued:Opened	Clin: Form unfreeze now. Kindly amend as appropriate. Thanks.
Dec-01-2020 16:08:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Candidate	Clin: DM, please unfreeze so site can update.
Dec-01-2020 10:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	kindly unfreeze and site will update to NALT Unknown
Nov-30-2020 21:01:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clin: Please update results if provided.
Nov-17-2020 17:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: INDETERMINATE	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-17-2020 17:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO RESULTS YIELDED YET	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-02-2020 10:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Dec-02-2020 08:03:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-02-2020 08:03:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NALT Unknown	Transcription Error

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

Dec-02-2020 00:01:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 1: Reissued:Opened	Clin: Form unfreeze now. Kindly amend as appropriate. Thanks.
Dec-01-2020 16:08:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Candidate	Clin: DM, please unfreeze so site can update.
Dec-01-2020 10:24:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	kindly unfreeze and site will update to NALT Unknown
Nov-30-2020 20:59:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clinical Query: Per CRF CRs 8.31.7, please provide manufacturer and test kit name. If not available, please enter if test conducted at 'CLIA-certified lab' or 'ISO 15189 accredited lab.' If both trade name and lab are not known, enter 'NALT Unknown.'
Nov-17-2020 17:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: UNKNOWN	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-30-2020 18:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 18:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-23-2021 12:29:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Feb-23-2021 12:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Nov-18-2020 09:19:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-18-2020 04:01:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 2: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-17-2020 17:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-17-2020 17:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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

Nov-17-2020 17:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of Collection: Nov/13/2020	Changed Information
Nov-17-2020 17:39:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-30-2020 18:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-17-2020 17:39:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Oct-30-2020 18:03:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: COVID-19 Tests done on 03OCT2020 and 14OCT2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-18-2020 09:19:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Sample ID: RW90624	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 09:19:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: RW90624	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-30-2020 18:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-30-2020 18:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-30-2020 18:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> 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
Oct-30-2020 18:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> COVID-19 Tests done on 03OCT2020 and 14OCT2020	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Form Version: 10-Oct-2020 15:59 **Form Status:** Data Complete, Frozen, Verified
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281103 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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I.a

Date	Location	User	Value	Reason
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**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
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-30-2020 18:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts:	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 18:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-30-2020 18:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts:	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 18:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.f

Date	Location	User	Value	Reason
Oct-30-2020 18:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Cont acts: NO	Initial Entry
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Cont acts:	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-30-2020 18:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001 Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form Version: 10-Oct-2020 15:59 Site No: 1128 Subject No: 11281103 Generated By: pfe.levisse				
Form: HEALTH CARE UTILIZATION - 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				
Nov-16-2020 18:23:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 2: Closed	Response satisfies query
Nov-16-2020 17:14:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Nov-16-2020 17:14:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	New Information
Nov-14-2020 08:40:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 2: Opened	Clin: As this subject was hospitalized, please enter on the CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Nov-09-2020 15:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Closed	Response satisfies query
Nov-09-2020 14:27:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	YES, PLEASE SEE ANSWER TO SERIOUS ADVERSE EVENT. REPORTED AS EVENT NUMBER 2020405778
Nov-05-2020 23:05:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	If hospitalized, have you reported SAE?
Oct-30-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: HOSPITALIZATION DETAILS - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Oct-30-2020 18:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Dec-09-2020 13:18:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-09-2020 13:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-30-2020 18:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Dec-09-2020 19:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Dec-09-2020 13:18:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-09-2020 13:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-09-2020 13:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Transcription Error
Dec-09-2020 08:37:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Opened	Clin: If subject was hospitalized, this information should be available. Please make every effort to obtain.
Dec-07-2020 11:49:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	all updated to N/A
Dec-07-2020 10:55:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Opened	Clin: Per response, please update HLTHCARE, LAB CHEM, LAB HEM, and any other applicable CRFs in this visit.

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020**Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Dec-02-2020 17:31:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	Has the subject been hospitalized due to POTENTIAL COVID-19 illness? Yes, subject thought she had COVID due to the ongoing diarrhea, which she was hospitalized for, and later diagnosed with SAE term.
Dec-02-2020 10:45:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Opened	Clin: It appears subject was hospitalized for SAEs and not potential COVID illness, please confirm.
Dec-02-2020 08:09:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	unfreeze HLTHCARE CRF and "No" will be updated to "Yes"
Dec-01-2020 19:20:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clin: As hospitalization = No on HLTHCARE CRF. Please update.
Oct-30-2020 18:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Dec-09-2020 13:18:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-09-2020 13:18:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Transcription Error
Oct-30-2020 18:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Oct/16/2020	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Dec-09-2020 13:18:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

Dec-09-2020 13:18:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Transcription Error
Oct-30-2020 18:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO Discharge Date: Oct/17/2020	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Oct-30-2020 18:19:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-30-2020 18:19:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Oct-30-2020 18:19:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Oct-30-2020 18:19:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-30-2020 18:19:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-30-2020 18:19:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020**Form:** ILLNESS DETAILS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-30-2020 17:46:55 (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
Nov-17-2020 17:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	New Information
Nov-03-2020 16:33:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Closed	Response satisfies query
Nov-02-2020 20:21:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	per DM, SAE has been undeleted
Nov-01-2020 14:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Opened	Clin: My apologies for the mistake, since GASTROENTERITIS is a SAE with a negative SARS-CoV-2 result should be documented on the COVID-19 CRF ILLNESS DETAILS form and should be also captured on the AE CRF page, please do not delete from the AE CRF form.
Oct-30-2020 17:46:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Gastroenteritis Date of Diagnosis: Oct/20/2020	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

Oct-30-2020 17:46:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: 3	Initial Entry
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090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** ILLNESS DETAILS - SEVERE - Audit Trail
Form Version: 17-Jul-2020 21:55 **Form Status:**
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281103 **Subject Initials:** ---
Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Oct-30-2020 17:53:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-10-2020 10:39:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharreda Cornes (pfe.cornes09)	Query 1: Closed	resolved
Nov-09-2020 14:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	source updated
Nov-05-2020 23:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Please provide the source for this page, thanks
Nov-01-2020 07:12:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-01-2020 07:11:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-30-2020 17:53:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE COVID-19 ILLNESS	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Nov-01-2020 07:12:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Nov-01-2020 07:11:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Oct-30-2020 17:48:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Nov-01-2020 11:12:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Nov-01-2020 07:12:37	ACV0PFEINFP6000	Jen Vasilio	Data Entry:	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001 Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form Version: 17-Jul-2020 21:55 Site No: 1128 Subject No: 11281103 Generated By: pfe.levisse				
Form: ILLNESS DETAILS - SEVERE - 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				
(UTC-06:00) Central Time (US & Canada)		(pfe.jvasilio)	Not Applicable	
Nov-01-2020 07:11:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Nov-01-2020 06:39:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	data will be removed
Oct-31-2020 17:46:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clinical Query: This CRF should only be completed for significant renal, hepatic or neurological dysfunction as part of the potential COVID illness.
Oct-30-2020 17:53:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES <i>Diagnosis:</i> Gastroenteritis Start Date: Oct/3/2020 Ongoing?: NO End Date: Oct/17/2020	Initial Entry
4. Toxicity Grade:				
Date	Location	User	Value	Reason
Nov-01-2020 07:12:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Nov-01-2020 07:11:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Oct-30-2020 17:53:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: 3	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 30-Jul-2020 21:27**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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. Lab Panel:**

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-10-2020 10:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharreda Cornes (pfe.cornes09)	Query 1: Closed	Response satisfies query
Nov-09-2020 14:44:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	awaiting records
Nov-05-2020 23:13:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Per source, labs were drawn. Please complete and provide the source, thanks
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Result::	Unknown
			Not Done::	Unknown
			Lab Normal Range:	Unknown

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 30-Jul-2020 21:27**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Lab Normal Range:	Unknown
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 30-Jul-2020 21:27**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 30-Jul-2020 21:27**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 30-Jul-2020 21:27**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 30-Jul-2020 21:27**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020**Form Version:** 30-Jul-2020 21:28**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-10-2020 10:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharreda Cornes (pfe.cornes09)	Query 1: Closed	Response satisfies query
Nov-09-2020 14:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	awaiting records
Nov-05-2020 23:13:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Per source, labs were drawn. Please complete and provide the source, thanks
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown	Initial Entry

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020
Form Version: 30-Jul-2020 21:28
Site No: 1128
Subject No: 11281103
Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
Form Status: Data Complete, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

			Result::	Unknown
			Not Done::	Unknown
			Lab Normal Range:	Unknown

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown	Initial Entry

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020
Form Version: 30-Jul-2020 21:28
Site No: 1128
Subject No: 11281103
Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
Form Status: Data Complete, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

			Lab Normal Range:	Unknown
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020
Form Version: 30-Jul-2020 21:28
Site No: 1128
Subject No: 11281103
Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
Form Status: Data Complete, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 30-Jul-2020 21:28**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 30-Jul-2020 21:28**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020
Form Version: 30-Jul-2020 21:28
Site No: 1128
Subject No: 11281103
Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
Form Status: Data Complete, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

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Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 30-Jul-2020 21:28**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 30-Jul-2020 21:28**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Unknown Test:: Unknown Result:: Unknown Not Done:: Unknown Lab Normal Range: Unknown	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Oct-30-2020 18:24:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Nov-10-2020 10:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharreda Cornes (pfe.cornes09)	Query 1: Closed	resolved
Nov-09-2020 14:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	awaiting records
Nov-05-2020 23:14:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Please provide the source for this page, thanks
Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Record Identifier:: Unkno wn Systolic:: Unkno wn Diastolic:: Unkno wn Respiratory Rate in respirati ons/minute: Unkno wn Heart Rate in beats/minute: Unkno wn	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

2.a Diastolic:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Nov-10-2020 10:38:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharreda Cornes (pfe.cornes09)	Query 1: Closed	resolved
Nov-09-2020 14:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	awaiting records
Nov-05-2020 23:14:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Please provide the source for this page, thanks
Oct-30-2020 18:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-30-2020 18:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Record Identifier:: Unknown Oxygen Saturation: Unknown	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-30-2020 18:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Oct-30-2020 18:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History
Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281103 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Nov-10-2020 10:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharreda Cornes (pfe.cornes09)	Query 1: Closed	Response satisfies query
Nov-09-2020 14:45:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	awaiting records
Nov-05-2020 23:15:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Please provide the source for this page, thanks
Oct-30-2020 18:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Oct-30-2020 18:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Oct-30-2020 18:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-02-2020 05:33:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Closed	Query text error, requery on dov
Nov-02-2020 04:50:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Opened	DM: Per comment, please update medical history once data is available. Thank you.
Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Nov-10-2020 10:39:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharreda Cornes (pfe.cornes09)	Query 1: Closed	Response satisfies query
Nov-09-2020 14:30:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	medical records not received. once received, site will update.
Nov-05-2020 23:15:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Please provide the source for this page, thanks

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry
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5. Start Date:

Date	Location	User	Value	Reason
Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-30-2020 18:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Oct/14/2020**Form:** IMAGING - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 10:39:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sharreda Cornes (pfe.cornes09)	Query 1: Closed	resolved
Nov-09-2020 14:29:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	medical records not received. once received, site will update.
Nov-05-2020 23:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Please provide the source for this page, thanks
Oct-30-2020 18:26:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-30-2020 18:26:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-30-2020 18:26:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Oct-30-2020 18:26:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Unknown	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Dec-18-2020 01:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 9: Closed	Closed as data updated.
Dec-17-2020 12:22:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 9: Answered	Changed data per query
Dec-17-2020 03:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 6: Closed	Response satisfies query
Dec-17-2020 02:12:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jayesh Yeole (pfe.yeolej)	Query 9: Opened	DM: On COVID TEST form, deleted logline is present. Please undelete logline and then erase all data. Post all data erased, 'Not Applicable' option will be available to select at form level comment. Kindly update COVID TEST form accordingly else clarify.
Dec-14-2020 02:50:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 6: Reissued:Candidate	Issue added in DM ops tracker.
Dec-13-2020 05:53:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 6: Answered	Kindly refer to comment from 08DEC2020: "initial page as well as swab page are not allowing site to add a form level comment of n/a". Please note there is no way to select n/a, however a comment has been made
Dec-11-2020 05:38:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Lina Gaikwad (pfe.gaikwl)	Query 6: Reissued:Opened	Kindly delete the current Item Level comment from the 'SELF SWAB' eCRF then add form level comment as 'Not Applicable' on 'SELF

Header Text: c4591001 Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020 Form Version: 22-Apr-2020 21:03 Site No: 1128 Subject No: 11281103 Generated By: pfe.levisse					Form: DATE OF VISIT - ILLNESS ONSET - 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				
					SWAB' form as needed. Update the data then change this query status to answered. Thank you.				
Dec-09-2020 16:35:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Query 6: Answered		Not Applicable has been selected on "self SWAB"				
Dec-08-2020 23:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe mahadp07)	Query 6: Reissued:Opened		DM: Thank you for response. Kindly refer CCG section '4.11.3. Deletion of an Item Level or Form Level Comment'. Once comment is removed on 'SELF SWAB' form, add form level comment 'Not Applicable' on 'SELF SWAB' form as needed.				
Dec-08-2020 08:35:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 6: Answered		all pages that would allow for the form level comment of N/A have been completed, however initial page as well as swab page are not allowing site to add a form level comment of n/a				
Dec-08-2020 01:34:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 6: Reissued:Opened		Forms are not frozen. Visit is marked as Erroneous and data is cleared on all initiated forms. Hence, kindly add Form level comment as 'Not applicable' on all the initiated forms of this visit to avoid yellow traffic light by using CCG section 4.10				
Dec-07-2020 10:18:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 6: Answered		kindly unfreeze all pages that have anything other than n/a, so that it can be updated to n/a, as the visit did not occur and instead Illness visits A				

Header Text: c4591001 Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020 Form Version: 22-Apr-2020 21:03 Site No: 1128 Subject No: 11281103 Generated By: pfe.levisse				
Form: DATE OF VISIT - ILLNESS ONSET - 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				
				was updated to include the symptoms reported at visit B, since it was within the timeframe.
Dec-07-2020 00:33:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 8: Deleted	DM query placed
Dec-07-2020 00:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 6: Reissued:Opened	DM : Visit is marked as Erroneous. However, Not Applicable as form level comment is not added on SELF SWAB form. Please review and update. Else, clarify.
Dec-03-2020 17:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 6: Answered	Form level comment is currently not blank and the date cannot be deleted. Prior to any additional queries, PLEASE VERIFY.
Dec-03-2020 10:04:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Dec-03-2020 10:00:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Deleted	Close Auto Query
Dec-03-2020 09:58:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Dec-02-2020 23:29:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 6: Reissued:Opened	Form level comments are currently blank. Please remove all entered data using the eraser icon. Once all entered data has been removed, an option to tick Not Applicable becomes available. Please update.

Header Text: c4591001 Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020 Form Version: 22-Apr-2020 21:03 Site No: 1128 Subject No: 11281103 Generated By: pfe.levisse				
Form: DATE OF VISIT - ILLNESS ONSET - 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-02-2020 17:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 6: Answered	The date cannot be deleted. There is no option to add a "Not Done" or N/A comment on the form level of this page. Please verify, prior to providing any additional guidance.
Dec-01-2020 23:14:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 6: Reissued:Opened	Response doesn't satisfy query. Form level comments are still blank/missing at this erroneous visit. Please update.
Dec-01-2020 10:18:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 6: Answered	Changed data per query
Dec-01-2020 00:23:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 6: Reissued:Opened	DM: Forms are not frozen. Visit is marked as Erroneous and data is cleared on all initiated forms. Hence, kindly add Form level comment as 'Not applicable' on all the initiated forms of this visit to avoid yellow traffic light by using CCG section 4.10.
Nov-30-2020 10:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 6: Answered	site cannot clear data as it may be frozen. please unfreeze so that site may complete task
Nov-30-2020 00:59:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 6: Reissued:Opened	If visit is erroneous: Any forms within the visit which haven't been started may be left blank. Any forms within the visit which were started in error should be cleared of all data entered and marked Not Applicable at the form level. Please update.
Nov-27-2020 15:15:22 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 6: Answered	Query is ambiguous

Header Text: c4591001 Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020 Form Version: 22-Apr-2020 21:03 Site No: 1128 Subject No: 11281103 Generated By: pfe.lewissc					Form: DATE OF VISIT - ILLNESS ONSET - 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				
(US & Canada)									
Nov-26-2020 03:16:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 6: Reissued:Opened	DM2: If visit initiated in error, add form level Not Done/Not Applicable comment to all forms with data entered in error. No update required to DOV CRF as it is marked 'Erroneous'.					
Nov-25-2020 08:23:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 6: Answered	date cannot be deleted, or marked as not done, kindly provide additional guidance. however marking erroneous should suffice, kindly confirm.					
Nov-25-2020 05:52:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Minal Pathak (pfe.patham13)	Query 6: Reissued:Opened	DM1: Page is now unfreezed. Please update the data.					
Nov-24-2020 13:55:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 6: Answered	site cannot make any changes to CRF. please enable site to make changes and site will try to delete date and visit type					
Nov-24-2020 00:42:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jayesh Yeole (pfe.yeolej)	Query 6: Opened	DM: 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.					
Nov-18-2020 11:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 5: Closed	Response satisfies query					
Nov-18-2020 10:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 5: Answered	Changed data per query					
Nov-18-2020 03:03:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 5: Opened	As this visit is marked as erroneous visit, please consider adding a form level comment					

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001 Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020 Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Frozen, Verified Site No: 1128 Site Name: (1128) Ventavia Research Group Subject No: 11281103 Subject Initials: --- Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 11:25				
				"not applicable" by removing data recorded on initiated CRFs under this visit.
Nov-18-2020 03:03:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 4: Deleted	Erroneous Visit is marked
Nov-18-2020 03:02:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 3: Deleted	Erroneous Visit is marked
Nov-17-2020 17:15:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Nov-17-2020 17:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-17-2020 17:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-13-2020 14:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-13-2020 14:44:56 (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.
Nov-13-2020 14:44:56 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)				Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-13-2020 14:44:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/13/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Dec-03-2020 10:04:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: ERRONEOUS VISIT	Initial Entry
Dec-03-2020 10:00:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry:	Transcription Error
Dec-03-2020 09:58:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: ERRONEOUS VISIT	Initial Entry
Dec-02-2020 17:33:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Nov-17-2020 17:15:21 (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
Nov-13-2020 14:44:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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I. Date of Assessment:

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-29-2020 23:47:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Closed	Closed as per site response.
Nov-27-2020 15:14:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	visit was completed in error. per DM instructions, Not done form level comment completed
Nov-25-2020 22:55:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW6243820;Date of Assessment is not expected to be Unknown or Not Done. Please review and update appropriately or clarify
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

Central Time (US & Canada)				
Nov-17-2020 17:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/13/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-29-2020 22:27:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 2: Closed	Response satisfies query
Nov-27-2020 15:14:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	visit was completed in error. per DM instructions, Not done form level comment completed
Nov-25-2020 23:10:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Opened	DMW6243824;Date First Symptom Started is not expected to be Unknown or Not Done. Please review

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Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020
Form Version: 10-Oct-2020 16:02
Site No: 1128
Subject No: 11281103
Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
Form Status: Data Complete, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

				and update appropriately or clarify
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 13:12:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Nov-18-2020 10:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:46:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued: Opened	Clin: For COVID A SELF SWAB, please enter barcode. For COVID B, please enter FORM LEVEL comment of Not Applicable to CRFs now that all data was moved.
Nov-17-2020 17:40:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Nov-17-2020 17:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued: Opened	Clin: Please confirm SELF SWAB and HLHCARE data was moved to COVID A Visit.
Nov-17-2020 17:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

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

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Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-17-2020 17:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-17-2020 17:03:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Opened	Clin: Please see Protocol Section 8.13 and CRF CRs Section 8.30.5,"If new symptoms are experienced during the SAME illness visit period, the symptoms should be added to the existing signs and symptoms form (a new illness visit should not be initiated)."
Nov-17-2020 16:48:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	kindly provide protocol section to support this request.
Nov-17-2020 07:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Reissued:Opened	Clin: If symptoms occurred during the COVID_A time period, they should be added to that COVID Visit and this overlapping visit should be removed.
Nov-16-2020 17:31:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	PER THE SUBJECT NOTED SYMPTOMS STARTED ON 14 OCT 2020 WHEN SUBJECT WAS ASKED ON 13NOV2020. SUBJECT DID NOT DISCLOSE THESE SYMPTOMS ON 14OCT2020 TELEHEALTH VISIT. OTHER SYPMTOMS WERE NEW.

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

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

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Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-14-2020 21:44:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clin: COVID_A SOD symptoms recorded from 03Oct-17Oct2020. Please confirm.
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Oct/14/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-30-2020 23:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Nov-30-2020 09:59:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	site currently cannot make changes to crf. eraser icon not available. perhaps crf is frozen? If so, please unfreeze crf so that site may complete request.
Nov-29-2020 22:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 1: Reissued:Opened	Form level comment is currently blank. Please remove all entered data using the eraser icon. Once all entered data has been removed, an option to tick Not Done becomes

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Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020
Form Version: 10-Oct-2020 16:02
Site No: 1128
Subject No: 11281103
Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
Form Status: Data Complete, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
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				available. Please update.
Nov-27-2020 15:14:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	visit was completed in error. per DM instructions, Not done form level comment completed
Nov-25-2020 23:11:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW6243825;Symptoms Ongoing is not expected to be Unknown or Not Done. Please review and update appropriately or clarify
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:14:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: FEVER Symptom Present: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: FEVER Symptom Present:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: FEVER Symptom Present: Not Applicable	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit
Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: FEVER Symptom Present: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: FEVER Symptom Present: Not Applicable	Initial Entry
Nov-17-2020 17:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: FEVER Symptom Present:	Changed Information
Nov-13-2020 14:48:53 (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
Nov-13-2020 14:48:53 (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
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicabl e	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 20:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clos ed	Auto closed by Validation Check: VC_CESOD006_08
Dec-02-2020 13:13:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Ans wered	Changed data per query
Dec-02-2020	ACV0PFEINFP6000	Thea Sonnier	Data Entry:	Initial Entry

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Header Text: c4591001 Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020 Form Version: 10-Oct-2020 16:02 Site No: 1128 Subject No: 11281103 Generated By: pfe.levisse				
Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History Form Status: Data Complete, Frozen Site Name: (1128) Ventavia Research Group Subject Initials: --- Generated Time (GMT): 29-Mar-2021 11:25				
13:13:14 (UTC-06:00) Central Time (US & Canada)		(pfe.tsonnier)	Not Applicable	
Dec-02-2020 00:09:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Reissued:Opened	DM : Symptoms Present is not expected to be Unknown or Not Done. Thus, Please review and consider to update the form level comment as Not Applicable. Else, clarify.
Dec-01-2020 10:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Dec-01-2020 05:20:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 1: Reissued:Opened	If visit is erroneous: Any forms within the visit which were started in error should be cleared of all data entered and marked Not Applicable at the form level, not the item level. Please update.
Nov-27-2020 15:14:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	visit was completed in error. per DM instructions, Not done form level comment completed
Nov-25-2020 23:14:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW6243826;Symptoms Present is not expected to be Unknown or Not Done. Please review and update appropriately or clarify
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

Nov-17-2020 17:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Pre Not Applicable sent:	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Pre sent:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Pre Not Applicable sent:	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Pre Not Done sent:	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Pre Not Applicable sent:	Initial Entry
Nov-17-2020 17:12:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Pre sent:	Changed Information

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

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

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Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

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Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Pre NO sent:	Initial Entry
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4.b Symptoms:

Date	Location	User	Value	Reason
Nov-13-2020 14:48:53 (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
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:12:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptom s: NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

			Symptom Present: Not Applicable	
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: Not Applicable	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: Not Applicable	Initial Entry
Nov-17-2020 17:12:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-13-2020 14:48:53 (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
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 10:02:16 (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 2 - Unscheduled Visit on Nov/13/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-17-2020 17:12:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: CHILLS Symptom Present: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: CHILLS Symptom Present:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: CHILLS Symptom Present: Not Applicable	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: CHILLS Symptom Present: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: CHILLS Symptom Present: Not Applicable	Initial Entry
Nov-17-2020 17:13:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: CHILLS Symptom Present:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**4.d Symptoms:**

Date	Location	User	Value	Reason
Nov-13-2020 14:48:53 (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
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:13:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P Not Applicable resent:	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P resent:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P Not Applicable resent:	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P Not Done resent:	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P Not Applicable resent:	Initial Entry
Nov-17-2020 17:13:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P resent:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P YES resent:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-13-2020 14:48:53 (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
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:13:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (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
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Dec-02-2020 13:13:14 (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
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: Not Done	Initial Entry
Nov-18-2020 10:02:16 (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
Nov-17-2020 17:13:22 (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
Nov-13-2020 14:48:53 (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

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**4.f Symptoms:**

Date	Location	User	Value	Reason
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:13:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED S ORE THROAT Symptom P Not Applicable resent:	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED S ORE THROAT Symptom P resent:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

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

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED S ORE THROAT Symptom P Not Applicable resent:	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levissc

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

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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4.g				
Date	Location	User	Value	Reason
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: NEW OR INCREASED S ORE THROAT Symptom P Not Done resent:	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED S ORE THROAT Symptom P Not Applicable resent:	Initial Entry
Nov-17-2020 17:13:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED S ORE THROAT Symptom P resent:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED S ORE THROAT Symptom P NO resent:	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**4.g Symptoms:**

Date	Location	User	Value	Reason
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NEW OR INCREASED SORE THROA T	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:13:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: DIARRHEA Symptom Present: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: DIARRHEA Symptom Present:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: DIARRHEA	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

(US & Canada)			Symptom Present: Not Applicable	
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: DIARRHEA Symptom Present: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: DIARRHEA Symptom Present: Not Applicable	Initial Entry
Nov-17-2020 17:13:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: DIARRHEA Symptom Present:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**4.h Symptoms:**

Date	Location	User	Value	Reason
Nov-13-2020 14:48:53 (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
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:13:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: VOMITING Symptom Present: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: VOMITING Symptom Present:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: VOMITING	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

(US & Canada)			Symptom Present: Not Applicable	
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: VOMITING Symptom Present: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: VOMITING Symptom Present: Not Applicable	Initial Entry
Nov-17-2020 17:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: VOMITING Symptom Present:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**4.i Symptoms:**

Date	Location	User	Value	Reason
Nov-13-2020 14:48:53 (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
Dec-17-2020 12:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-02-2020 13:13:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-25-2020 08:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Nov-18-2020 10:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-17-2020 17:12:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms - Other:	Changed Information
Nov-13-2020 14:49:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms - Other: FATIGUE	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form Version: 10-Oct-2020 16:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Nov-17-2020 17:12:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:49:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: FATIGUE	Initial Entry

Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
Form Version: 06-Jul-2020 21:54 **Form Status:**
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281103 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Dec-17-2020 11:58:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Undeleted	New Information
Dec-01-2020 10:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Deleted	New Information
Dec-01-2020 10:25:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Undeleted	Changed Information
Dec-01-2020 10:14:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Deleted	Transcription Error
Nov-13-2020 14:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Created	

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-02-2020 00:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 1: Closed	data deleted
Dec-01-2020 10:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Dec-01-2020 03:49:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Opened	In case no data to be reported, please delete this logline. Please delete this logline if no data to be reported. To delete, go in the Log Summary page and select the 'Delete' option at the bottom left of the screen and click 'Apply'.
Nov-17-2020 17:11:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/13/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:33 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)				
Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:11:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:11:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:11:57 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)				
Nov-13-2020 14:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME C ORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:11:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-13-2020 14:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-17-2020 17:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-17-2020 17:10:36 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Trade Name is Other, however Trade Name

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020
Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Form Version: 06-Jul-2020 21:54
Form Status: Data Complete, Frozen
Site No: 1128
Site Name: (1128) Ventavia Research Group
Subject No: 11281103
Subject Initials: ---
Generated By: pfe.levisse
Generated Time (GMT): 29-Mar-2021 11:25

(US & Canada)				Other, Specify is not completed. Please update.
Nov-16-2020 19:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Closed	Response satisfies query
Nov-16-2020 17:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-16-2020 17:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Trade Name is Other, however Trade Name Other, Specify is not completed. Please update.
Nov-16-2020 17:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Nov-16-2020 17:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: OTHER	Initial Entry
Nov-14-2020 11:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Josee Robillard (pfe.robilj01)	Query 1: Opened	Item incomplete

7. Test Result:

Date	Location	User	Value	Reason
Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:11:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-16-2020 19:26:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Closed	Response satisfies query
Nov-16-2020 17:11:43 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)				
Nov-16-2020 17:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NEGATIVE	Initial Entry
Nov-14-2020 11:33:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Josee Robillard (pfe.robilj01)	Query 1: Opened	Item incomplete

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

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8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Nov-16-2020 17:12:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	New Information
Nov-13-2020 14:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO RESULTS REPORTED YET	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-17-2020 12:16:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:10:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-16-2020 17:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: UNKNOWN	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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. Data Origin**

Date	Location	User	Value	Reason
Dec-17-2020 12:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:56:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Dec-16-2020 11:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-13-2020 14:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-17-2020 12:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:56:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Dec-16-2020 11:22:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-13-2020 14:50:56 (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
Dec-17-2020 12:17:09	ACV0PFEINFP6000	Thea Sonnier	Data Entry:	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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

(UTC-06:00) Central Time (US & Canada)		(pfe.tsonnier)	Not Applicable	
Dec-17-2020 11:56:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-07-2020 11:46:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Dec-01-2020 10:17:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-25-2020 08:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Nov-18-2020 10:04:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-17-2020 17:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 16:51:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-13-2020 14:50:56 (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.
Nov-13-2020 14:50:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of Collection: Nov/13/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 12:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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-17-2020 11:56:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:47:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-07-2020 11:47:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Dec-01-2020 10:17:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-25-2020 08:19:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Nov-18-2020 10:04:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-16-2020 11:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID:	Changed Information
Dec-16-2020 11:21:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: RW90624	Changed Information
Nov-18-2020 10:03:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: RW90624	New Information (DELETED)
Nov-13-2020 16:51:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: RW90624	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 14:07:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Josee Robillard (pfe.robilj01)	Query 1: Closed	Response satisfies query
Dec-16-2020 11:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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-16-2020 11:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-16-2020 11:21:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RW90624	Changed Information
Dec-16-2020 09:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Josee Robillard (pfe.robilj01)	Query 1: Opened	The entire form needs to be marked as NOT APPLICABLE. In order to do so, please undelete the Sample ID and then clear it out using the eraser. After, add a FORM level comment of Not Applicable.
Nov-18-2020 10:03:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RW90624	New Information (DELETED)
Nov-13-2020 16:51:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: RW90624	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020**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:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-17-2020 12:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Dec-07-2020 11:48:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:09:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-13-2020 14:51:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-17-2020 12:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Dec-07-2020 11:48:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:09:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-13-2020 14:51:19	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020
Form Version: 22-Apr-2020 21:03
Site No: 1128
Subject No: 11281103
Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

(UTC-06:00) Central Time (US & Canada)		(autocalc)	NASAL_SWAB	
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3. Sample Collected?

Date	Location	User	Value	Reason
Dec-17-2020 12:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:09:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-17-2020 17:09:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-17-2020 17:06:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Nov-13-2020 14:51:19 (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
Dec-17-2020 12:17:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:56:15 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

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: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)				
Dec-07-2020 11:48:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:06:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:51:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NOT EXPECTED, SUBJECT COMPLE TED HOME SELF SWAB	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: Not Done	Initial Entry
Nov-17-2020 17:04:58 (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
Nov-13-2020 14:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-13-2020 14:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:04:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits o r Contacts: Not Applicable	Initial Entry
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits o r Contacts:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits o r Contacts: Not Applicable	Initial Entry
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits o r Contacts: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Nov-17-2020 17:05:09 (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
Nov-13-2020 14:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-13-2020 14:52:12 (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
Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:05:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Dec-17-2020 12:17:41 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: PRIMARY CARE	Initial Entry

Header Text: c4591001 Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020 Form Version: 10-Oct-2020 15:59 Site No: 1128 Subject No: 11281103 Generated By: pfe.levisse					Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History Form Status: Data Complete, Frozen Site Name: (1128) Ventavia Research Group Subject Initials: --- Generated Time (GMT): 29-Mar-2021 11:25				
(US & Canada)				r: PHYSICIAN Occurrence of Visits or Contacts: Not Applicable					
Dec-17-2020 11:55:54 (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:	Initial Entry					
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: Not Applicable	Initial Entry					
Dec-01-2020 10:16:55 (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 Done	Initial Entry					
Nov-17-2020 17:05:23 (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					
Nov-13-2020 14:52:54 (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: YES <i>Number of Visits or Contacts:</i> 1	Transcription Error					
Nov-13-2020 14:52:12 (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: YES	Initial Entry					

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**I.c Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-13-2020 14:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:05:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-13-2020 14:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Transcription Error
Nov-13-2020 14:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Please provide number of Visits or contacts for each type of healthcare professional. If no visits or contacts were made, please enter 0.
Nov-13-2020 14:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

Dec-17-2020 12:17:41 (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
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: Not Done	Initial Entry
Nov-17-2020 17:05:33 (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
Nov-13-2020 14:52:12 (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

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Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)***I.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-13-2020 14:52:12 (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
Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:05:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

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Date	Location	User	Value	Reason
Dec-17-2020 12:17:41 (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
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts:	Initial Entry
Dec-07-2020 11:48:24	ACV0PFEINFP6000	Jen Vasilio	Data Entry:	Initial Entry

Header Text: c4591001 Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020 Form Version: 10-Oct-2020 15:59 Site No: 1128 Subject No: 11281103 Generated By: pfe.levisse					Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History Form Status: Data Complete, Frozen Site Name: (1128) Ventavia Research Group Subject Initials: --- Generated Time (GMT): 29-Mar-2021 11:25				
(UTC-06:00) Central Time (US & Canada)		(pfe.jvasilio)	Type of Practitioner: TELEPHONE CONSULTATION	Occurrence of Visits or Contacts: Not Applicable					
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION	Occurrence of Visits or Contacts: Not Done	Initial Entry				
Nov-17-2020 17:05:44 (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				
Nov-13-2020 14:52:12 (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 2 - Unscheduled Visit on Nov/13/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**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
Nov-13-2020 14:52:12 (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
Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:52:12 (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
Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or C Not Applic ontacts: able	Initial Entry
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or Conta cts:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)			Type of Practitioner: OTHER Occurrence of Visits or Contacts: Not Applicable	
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: Not Done	Initial Entry
Nov-17-2020 17:05:55 (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
Nov-13-2020 14:52:12 (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 2 - Unscheduled Visit on
Nov/13/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25***If Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-13-2020 14:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: OTHER	Initial Entry

If Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:05:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:52:12 (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
Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Dec-17-2020 12:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:04:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:52:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020**Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Dec-17-2020 12:21:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:04:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-13-2020 14:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Dec-17-2020 12:21:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:04:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-13-2020 14:54:05	ACV0PFEINFP6000	Thea Sonnier	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Nov/13/2020

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-06:00) Central Time (US & Canada)		(pfe.tsonnier)	Not Applicable	
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3. Admission Date:

Date	Location	User	Value	Reason
Dec-17-2020 12:21:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-17-2020 11:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u>	Initial Entry
Dec-07-2020 11:48:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-01-2020 10:16:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Not Done	Initial Entry
Nov-17-2020 17:04:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u>	Initial Entry
Nov-13-2020 14:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Not Applicable	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Dec-17-2020 12:21:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-17-2020 11:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u>	Initial Entry
Dec-07-2020 11:48:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-01-2020 10:16:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Not Done	Initial Entry
Nov-17-2020 17:04:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u>	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

Nov-13-2020 14:54:05 (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 2 - Unscheduled Visit on Nov/13/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281103 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-17-2020 12:21:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Dec-07-2020 11:48:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:01:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Nov-13-2020 14:53:16 (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
Dec-17-2020 12:21:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Dec-17-2020 11:55:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-07-2020 11:48:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Dec-01-2020 10:16:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-17-2020 17:01:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Nov-13-2020 14:53:16	ACV0PFEINFP6000	Thea Sonnier	Data Entry:	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on
Nov/13/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-06:00) Central Time
(US & Canada)

(pfe.tsonnier) NO

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-17-2020 12:21:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-17-2020 11:55:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u>	Initial Entry
Dec-07-2020 11:48:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-01-2020 10:16:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Not Done	Initial Entry
Nov-17-2020 17:01:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u>	Changed Information
Nov-13-2020 14:53:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> 1	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-11-2020 14:26:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Nov/11/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-11-2020 14:26:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: COVID_A1	Initial Entry

090177e196ae400d\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit on Nov/11/2020 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281103**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-11-2020 14:28:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-11-2020 14:28:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-11-2020 14:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-11-2020 14:28:22 (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.
Nov-11-2020 14:28:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES Date of Collection: Nov/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-11-2020 14:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BJ6SYG	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 14:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SYG	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Nov/11/2020 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.lewissc

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

5.b

Date	Location	User	Value	Reason
Nov-11-2020 14:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BJ6ST5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 14:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6ST5	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-11-2020 14:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BHXNNJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-11-2020 14:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BHXNNJ	Initial Entry

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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: 11281103

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 17:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sep/30/2020	Changed Information
Oct-04-2020 12:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-04-2020 12:05:41 (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 12:05:41 (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: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levissc

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
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1128) Ventavia Research Group

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Date	Location	User	Value	Reason
Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Nov-02-2020 20:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Undeleted	undeleted per DM
Nov-01-2020 07:20:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Deleted	Per DM, this event should not be listed as an AE, should only be listed on the COVID illness visit
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

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Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

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
Oct-16-2020 19:16:21 (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
Oct-16-2020 19:16:21 (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
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Kidney Stones	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Oct/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-13-2020 14:55:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date Time: Oct/22/2020 UNK:UNK	New Information
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-31-2020 00:43:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jayashree Gautam (pfe.gautaj02)	Query 1: Closed	Response satisfies query

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Subject No: 11281103

Generated By: pfe.levisse

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Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Oct-30-2020 17:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-30-2020 17:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: 2	Initial Entry
Oct-30-2020 17:05:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry:	Initial Entry
Oct-29-2020 11:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Opened	Please remove comment and report toxicity grade. Thank you.
Oct-16-2020 19:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Unknown	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
Nov-16-2020 15:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	ebone williams (pfe.willie35)	Query 3: Closed	data in paper source
Nov-13-2020 17:34:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 3: Opened	Please provide the source (in AE log) for hospitalization, thanks
Oct-20-2020 04:40:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Oct-19-2020 13:13:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	event was faxed to safety database, kindly verify as the site did receive a confirmation the fax went through.
Oct-17-2020 09:01:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: Kidney Stones(Onset date:03Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness

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Header Text: c4591001 Visit: Logs - Unscheduled Form Version: 22-Apr-2020 21:02 Site No: 1128 Subject No: 11281103 Generated By: pfe.levisse				
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History Form Status: Data Complete, Frozen, Not Complete Site Name: (1128) Ventavia Research Group Subject Initials: --- Generated Time (GMT): 29-Mar-2021 11:25				
				and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-16-2020 19:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-16-2020 19:20:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Transcription Error
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Kidney Stones: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

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Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Did this serious event require or prolong hospitalization? YES	Initial Entry
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-16-2020 20:04:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Macci Villarreal-Carreon (pfe.villam71)	Query 1: Closed	Response satisfies query
Nov-16-2020 17:01:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-16-2020 17:01:46 (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> RENAL CALCULUS	New Information
Nov-13-2020 17:33:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Per source, it is due to 'renal calculus'. Please verify and update, thanks
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> unknown etiology	Initial Entry

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Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-31-2020 02:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe ks66)	Query 1: Closed	Response satisfies query
Oct-30-2020 17:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-30-2020 17:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry
Oct-30-2020 17:07:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry:	Initial Entry
Oct-29-2020 11:24:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Opened	Please remove comment and report "Was a Non-Drug Treatment given? question with appropriate response. Thank you.
Oct-16-2020 19:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Unknown	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-14-2020 08:58:39 (UTC-06:00) Central Time	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	Response satisfies query

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(US & Canada)				
Nov-13-2020 20:22:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Closed	Auto closed by Validation Check: VC_AE001_35
Nov-13-2020 14:57:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 3: Answered	Changed data per query
Nov-13-2020 14:43:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Opened	DMW5377731;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Nov-13-2020 09:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Nov-13-2020 09:01:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RECOVERED/RESOLVED	New Information
Nov-13-2020 03:56:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2020405778,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-16-2020 19:17:48 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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(US & Canada)				
Oct-16-2020 19:17:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: RECO VERI NG/R ESOL VING	Transcription Error
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Kidney Stones: 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".
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: UNKN OWN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 19:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-20-2020 04:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020405778	Initial Entry

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Generated By: pfe.levissc

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I. Category:

Date	Location	User	Value	Reason
Oct-16-2020 19:22:58 (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
Oct-16-2020 19:22:58 (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
Dec-23-2020 17:42:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 4: Closed	Response satisfies query
Dec-22-2020 15:22:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 4: Answered	It is the site's understanding that only Imodium was used to treat Diarrhea and no final potassium levels were in medical records, only notations from Hospital doctor that potassium levels were "improved upon discharge".
Dec-21-2020 13:09:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 4: Reissued:Opened	Thank you for providing the information. Kindly add further details for: 1) rationale for use of antibiotic for diarrhea? 2) potassium levels after treatment. Thank you.
Dec-16-2020 16:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 4: Answered	Updated SAE per query
Dec-10-2020 21:38:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 4: Opened	CLINICAL_ Please submit a fu SAE report to provide details regarding: 1) UTI – antibiotic course (iv v po); 2)nephrolithiasis – workup including imaging and tx; 3)

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

				hypokalemia – tx course, repeat potassium; 4) diarrhea – reason for antibiotics.
Nov-26-2020 05:14:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 3: Closed	Response satisfies query
Nov-25-2020 08:54:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Nov-25-2020 08:54:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Severe Hypokalemia	New Information
Nov-25-2020 04:48:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 3: Opened	SAE RECON:AER#2020405778, the term in AE CRF was reported as 'Low potassium' while retained as 'severe hypokalemia' in Safety database. Please confirm correct term. If safety update is required, please submit a follow-up form.
Nov-03-2020 16:33:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Closed	Response satisfies query
Nov-03-2020 06:57:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 2: Closed	Response satisfies query
Nov-02-2020 20:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	undeleted per DM as the event is an SAE
Nov-02-2020 20:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	undeleted per DM
Nov-02-2020 07:01:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 2: Opened	SAE RECON:AER#2020405778, Gastroenteritis event was deleted in AE CRF however, retained as Serious event in Safety database. Please confirm if event is valid SAE and should be retained in CRF, Otherwise, please submit a ffup AE form to update SDB.

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Nov-01-2020 14:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: My apologies for the mistake, since GASTROENTERITIS is a SAE with a negative SARS-CoV-2 result should be documented on the COVID-19 CRF ILLNESS DETAILS form and should be also captured on the AE CRF page, please do not delete from the AE CRF form.
Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Low potassium	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Oct/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-13-2020 14:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date Time: Oct/22/2020 UNK:UNK	New Information
Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-31-2020 03:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alfia Mannan (pfe.mannaa)	Query 1: Closed	Response satisfies query
Oct-30-2020 17:08:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-30-2020 17:08:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: 2	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Oct-30-2020 17:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry:	Initial Entry
Oct-29-2020 11:25:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	Please remove comment and report toxicity grade question with appropriate response. Thank you.
Oct-16-2020 19:23:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Unknown	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
Nov-16-2020 20:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Macci Villarreal-Carreon (pfe.villam71)	Query 2: Closed	Response satisfies query
Nov-16-2020 17:04:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	Changed data per query
Nov-13-2020 17:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Opened	'YES' box is not checked for SAE and also hospitalization is not provided in the source (AE log in Complion), thanks
Oct-20-2020 04:40:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Oct-19-2020 13:13:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	event was faxed to safety database, kindly verify as the site did receive a confirmation the fax went through.
Oct-17-2020 09:02:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:Low potassium(Onset date:03Oct2020) is not reported to Safety database but marked serious on AE CRF.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

				Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Low potassium: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

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Date	Location	User	Value	Reason
Nov-16-2020 20:04:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Macci Villarreal- Carreon (pfe.villam71)	Query 1: Closed	Response satisfies query
Nov-16-2020 17:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-16-2020 17:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NOT RELATED If Not Related to study treatment(s), th is event is due to: OTHER <i>If Other, specify:</i> HYPOKALEMIA	New Information
Nov-13-2020 17:37:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Per source it is due to 'hypokalemia'. Please verify and update, thanks
Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT RELATED If Not Related to study treatment(s), th is event is due to: OTHER <i>If Other, specify:</i> unknown etiology	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281103

Generated By: pfe.levissc

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Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-31-2020 04:12:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Prithvee R (pfe rp21)	Query 1: Closed	Response satisfies query
Oct-30-2020 17:08:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-30-2020 17:08:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry
Oct-30-2020 17:08:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry:	Initial Entry
Oct-29-2020 11:25:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Opened	Please remove comment and report "Was a Non-Drug Treatment given?" question with appropriate response. Thank you.
Oct-16-2020 19:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Unknown	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-14-2020 08:59:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query

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Header Text: c4591001

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Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-13-2020 20:22:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Clo sed	Auto closed by Validation Check: VC_AE001_35
Nov-13-2020 14:57:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Ans wered	Changed data per query
Nov-13-2020 14:43:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Op ened	DMW5377730;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Nov-13-2020 09:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	New Information
Nov-13-2020 09:01:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry : RECO VERE D/RE SOLV ED	New Information
Nov-13-2020 03:57:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Op ened	SAE RECON:AER#2020405778,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.

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Site Name: (1128) Ventavia Research Group

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Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry : RECO VERI NG/R ESOL VING	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-16-2020 19:22:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-20-2020 04:39:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020405778	Initial Entry

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Site No: 1128

Subject No: 11281103

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Nov-01-2020 07:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry
Nov-01-2020 07:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	New Information
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-01-2020 07:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry
Nov-01-2020 07:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	New Information
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-14-2020 09:00:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 5: Closed	Response satisfies query
Nov-13-2020 09:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	New Information
Nov-13-2020 09:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Escherichia coli urinary tract infection	New Information
Nov-13-2020 02:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 5: Opened	SAE RECON: AER#2020405778,the term was updated to 'Escherichia coli urinary tract infection' in Safety

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Generated By: pfe.levisse

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				database while recorded as 'GASTROENTERITIS' in AE CRF. Please confirm correct term.If safety update is required, please submit a follow-up form
Nov-01-2020 14:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 4: Closed	Response satisfies query
Nov-01-2020 07:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> GASTROENTERITIS	Initial Entry
Nov-01-2020 07:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u>	New Information
Nov-01-2020 07:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 4: Answered	removed per DM
Oct-31-2020 14:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 4: Reissued:Opened	Clin: Per protocol section 8.3.7., COVID-19 related GASTROENTERITIS does not qualify as AE and please should be documented only on the COVID-19 CRF ILLNESS DETAILS form as BRONCHITIS and should not be captured on the AE CRF page.
Oct-30-2020 18:35:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 4: Answered	done
Oct-27-2020 21:49:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 4: Opened	Clin: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available and a NASAL SWAB will not be collected.
Oct-27-2020 21:48:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Closed	Response satisfies query

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Header Text: c4591001 Visit: Logs - Unscheduled Form Version: 22-Apr-2020 21:02 Site No: 1128 Subject No: 11281103 Generated By: pfe.levisse				
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History Form Status: Data Complete, Frozen, Not Complete Site Name: (1128) Ventavia Research Group Subject Initials: --- Generated Time (GMT): 29-Mar-2021 11:25				
Oct-27-2020 21:46:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguerrouh (pfe.bougus)	Query 1: Reissued:Opened	Clin: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured only on the SOD CRF form and a NASAL SWAB will not be collected.
Oct-26-2020 16:42:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	subject was hospitalized, therefore COVID illness visit not done. PD recorded and PI notified.
Oct-25-2020 19:40:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguerrouh (pfe.bougus)	Query 1: Reissued:Opened	Clin: Per protocol section 8.1., potential COVID-19 related GASTROENTERITIS (FEVER, DIARRHEA, VOMITING), should have please triggered a COVID Illness Visit irrespective of perceived etiology or clinical significance. Please complete the COVID-19 CRF forms
Oct-25-2020 17:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 3: Closed	Response satisfies query
Oct-25-2020 16:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 3: Answered	These were a set of symptoms indicating gastroenteritis.
Oct-22-2020 15:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 3: Opened	GPDClin: Per SAE report, on 10/9/20, the subject reported symptoms of shortness of breath, sore throat, vomiting, fever. Please clarify if the symptoms led to hospitalization were those symptoms or a different set of symptoms indicating gastroenteritis.
Oct-22-2020 10:12:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 2: Closed	Response satisfies query

Header Text: c4591001
Visit: Logs - Unscheduled
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Generated By: pfe.levisse

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Oct-21-2020 18:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-21-2020 18:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-21-2020 18:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: GASTROENTERITIS	New Information
Oct-20-2020 13:59:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 2: Opened	GPDClin: Please clarify the infection location, organ or system, e.g., UTI, Upper respiratory tract infection, etc.
Oct-20-2020 11:03:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: Per protocol section 8.1., potential COVID-19 related UNKNOWN INFECTION should have please triggered a COVID Illness Visit irrespective of perceived etiology or clinical significance and a nasal swab collected ASAP.
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: unknown infection	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-01-2020 07:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Oct/3/2020 UNK:UNK	Initial Entry
Nov-01-2020 07:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	New Information
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Oct/3/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-11-2020 16:43:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date Time:	New Information

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281103**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

			Oct/22/2020 UNK:UNK	
Nov-01-2020 07:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES	Initial Entry
Nov-01-2020 07:18:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	New Information
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-31-2020 04:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	N Swapna Sree (pfe.sreen)	Query 1: Closed	Response satisfies query
Oct-30-2020 17:10:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-30-2020 17:10:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: 2	Initial Entry
Oct-30-2020 17:10:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry:	Initial Entry
Oct-29-2020 11:26:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	Please remove comment and report toxicity grade question with appropriate response. Thank you.
Oct-16-2020 19:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Unknown	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
Nov-16-2020 16:19:25 (UTC-06:00) Central Time	ACV0PFEINFP6000	ebone williams	Query 2: Closed	Noted in paper source

Header Text: c4591001

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Subject No: 11281103

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

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(US & Canada)		(pfe.willie35)		
Nov-13-2020 17:42:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Opened	Please provide the source (in AE log) for hospitalization, thanks
Oct-20-2020 04:39:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.qitor)	Query 1: Closed	Response satisfies query
Oct-19-2020 13:13:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	event was faxed to safety database, kindly verify as the site did receive a confirmation the fax went through.
Oct-17-2020 09:02:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.qitor)	Query 1: Opened	SAE RECON: unknown infection(Onset date:03Oct2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE unknown infection: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Generated By: pfe.levisse

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

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

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Nov-16-2020 20:05:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Macci Villarreal- Carreon (pfe.villam71)	Query 2: Closed	Response satisfies query
Nov-16-2020 17:08:08 (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 du e to: OTHER <i>If Other, speci fy:</i> BACTERIA L INFECTI ON	New Information
Nov-16-2020 17:06:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	Changed data per query
Nov-13-2020 17:41:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Opened	Discrepancy: In source it is due to 'viral infection' while it is E. Coli UTI which is bacterial. Please verify with Dr. Koch and update (all data should match), thanks
Nov-12-2020 13:54:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Closed	Response satisfies query
Nov-12-2020 10:03:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-12-2020 10:03:55 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NOT RELATED If Not Related to study treatment(s	New Information

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<p>& Canada)</p>			<p>), this event is due to:</p> <p>OTHER</p> <p><i>If Other, specify:</i></p> <p>Escherichia coli Urinary tract infection</p>	
<p>Nov-12-2020 04:54:51 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000.InFormAdapter.Discrepancy</p>	<p>PFE SDQ PROD (pfe.PFESDQ_PROD)</p>	<p>Query 1: Opened</p>	<p>Please review "If not related to study treatment other" field, the following text was indicated in the comment field [viral infection]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[suryas18 SDQ=48196]"</p>
<p>Nov-11-2020 16:44:24 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Thea Sonnier (pfe.tsonnier)</p>	<p>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p><i>If Other, specify:</i></p> <p>viral infection</p>	<p>New Information</p>
<p>Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Jen Vasilio (pfe.jvasilio)</p>	<p>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:</p>	<p>Initial Entry</p>

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Header Text: c4591001

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Subject No: 11281103

Generated By: pfe.levisse

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			OTHER	
			<i>If Other, specify:</i>	
			unknown etiology	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-01-2020 00:00:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	S Vijaya Kumar (pfe.kumas557)	Query 1: Closed	Data updated.
Oct-30-2020 17:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-30-2020 17:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry
Oct-30-2020 17:10:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry:	Initial Entry
Oct-29-2020 11:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	Please remove comment and report "Was concomitant medication given?" question with appropriate response. Thank you.
Oct-16-2020 19:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Unknown	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-01-2020 00:01:33 (UTC-06:00) Central Time	ACV0PFEINFP6000	Karan Somasundar	Query 1: Closed	Response satisfies query

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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(US & Canada)		(pfe.somask04)		
Oct-30-2020 17:11:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-30-2020 17:11:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry
Oct-30-2020 17:10:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry:	Initial Entry
Oct-29-2020 11:26:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	Please remove comment and report "Was a Non-Drug Treatment given?" question with appropriate response. Thank you.
Oct-16-2020 19:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Unknown	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-13-2020 02:48:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Closed	outcome updated in SDB
Nov-12-2020 15:29:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 3: Answered	kindly confirm what SDB is.
Nov-12-2020 12:51:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 3: Opened	SAE RECON:AER#2020405778 ,outcome was updated to RECOVERED/RESOLVED in AE CRF however, reported as RECOVERING/RESOLVING on SDB. Please confirm correct outcome. If safety update is required, please submit a follow-up form
Nov-11-2020 16:44:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-11-2020 16:44:00 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RECOVERED/RESOLVED	New Information

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Header Text: c4591001

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

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(US & Canada)				
Nov-11-2020 16:43:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE GASTROENTERITIS: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-16-2020 19:25:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-16-2020 19:25:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: RECOVERING/RESOLVING	Transcription Error
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE unknown infection: 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".
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: UNKNOWN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-16-2020 19:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-20-2020 04:39:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020405778	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - 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: 11281103

Subject Initials: ---

Generated By: pfe.levisse

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 16:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Jan/19/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281103

Subject Initials: ---

Generated By: pfe.levissc

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
Feb-24-2021 16:20:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1 /2	New Information
Jan-20-2021 16:30:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

090177e196ae400d\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:** 11281103**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[Back to Form](#)**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-20-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Jan/19/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-24-2021 23:54:58 (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_35
Feb-24-2021 16:20:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Feb-24-2021 05:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Reissued:Opened	DM: 'FURTHER VACCINATION CONFIRMATION' CRF is unfrozen, kindly review and update.
Feb-24-2021 03:18:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Reissued:Candidate	DM: 'FURTHER VACCINATION CONFIRMATION' CRF is unfrozen, kindly review and update.
Feb-23-2021 11:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	please unfreeze REVAX CONT so that site and make changes
Feb-22-2021 13:20:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7350173;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF.

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

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				Please review and update as appropriate.
Jan-20-2021 16:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: ASSESS ELIG IBILITY FOR ADDITIONAL VACCINATIO N	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281103

Generated By: pfe.levisc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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1. Subject Status

Date	Location	User	Value	Reason
Oct-04-2020 12:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-12-2020 16:04:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-12-2020 15:54:32 (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
Oct-05-2020 17:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/30/2020	Changed Information
Oct-04-2020 12:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry
Aug-12-2020 16:04:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/12/2020	Initial Entry
Aug-12-2020 15:54:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/12/2020	Initial Entry

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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281103

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: ---

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-22-2020 16:27:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

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Cohort Selection

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

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

Header Text: c4591001	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: 11281123	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.lewissc	

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Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/17/2020

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[11281123]
2.	Birth Date:	(b) (6)/1982
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281123

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

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	Aug/18/2020
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: 11281123

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Facial Acne]
	Start Date:	Jun/UNK/2020
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Migraine Headaches]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Headaches]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

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:	[Drug Allergy: Z-pack]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[History of Shingles]
	Start Date:	UNK/UNK/2006
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281123

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:	Aug/18/2020
2.	Weight:	[135.9]
3.	Unit:	LB
4.	Height:	[61.5]
5.	Unit:	in
6.	Body Mass Index:	[25.3]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/18/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

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 :	Aug/17/2020
2.	Randomization Number:	[50728]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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: Aug/17/2020
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	[BK8CWZ]
5.b	Sample ID	[BK8CX0]
5.c	Sample ID	[BGH7LH]
5.d	Sample ID	[BGH7LJ]
5.e	Sample ID	[BGH7LK]

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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/17/2020
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	[BGH7RR]
-----	-----------	----------

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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/18/2020 16:17
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

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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:	Sep/9/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[96.5]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

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

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/9/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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: Sep/9/2020
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	[BP9WM7]
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090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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:	Sep/9/2020 10:40
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

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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	Oct/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

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: Oct/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	[BHXNGM]
5.b	Sample ID	[BJ6SL8]
5.c	Sample ID	[BJ6SGC]

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Mar/5/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

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

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/5/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPG2N]
5.b	Sample ID	[BS885L]
5.c	Sample ID	[BS8891]

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

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

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levissc

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

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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090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/18/2020

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: 11281123

Subject Initials: ---

Generated By: pfe.lewissc

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Aug/18/2020
2.	Erroneous Visit	ERRONEOUS VISIT

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/18/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.lewissc

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	Not Done	Comments
----	-------------	----------	--------------------------

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levissc

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

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

Contact Outcome

1.	Contact Type:	Not Done _____	Comments
2.	Was contact made?	Not Done _____	Comments
3.	Comments:	Not Done _____ []	Comments

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/18/2020

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levissc

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

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

Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	Temperature:	Not Done _____ []	Comments
	Unit:	Not Done _____	Comments
	Temperature Location:	Not Done _____	Comments

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Aug/18/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281123**Generated By:** pfe.levissc**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT**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](#)**Unplanned Assessment Of Local Reaction**

1.	Date of Assessment:	Not Done _____ //	Comments
2.	Injection Site Location	Not Done _____	Comments
3.	Injection Site Body Side:	Not Done _____	Comments

Reaction

4.a	Reaction:	REDNESS	
	Reaction Present:	Not Done _____	Comments
4.b	Reaction:	SWELLING	
	Reaction Present:	Not Done _____	Comments

Symptom

5.a	Symptom:	PAIN AT INJECTION SITE	
	Symptom Present:	Not Done _____	Comments
5.b	Symptom:	FATIGUE/TIREDNESS	
	Symptom Present:	Not Done _____	Comments
5.c	Symptom:	HEADACHE	
	Symptom Present:	Not Done _____	Comments
5.d	Symptom:	VOMITING	
	Symptom Present:	Not Done _____	Comments

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

5.e	Symptom:	DIARRHEA	
	Symptom Present:	Not Done _____	Comments
5.f	Symptom:	NEW OR WORSENERD MUSCLE PAIN	
	Symptom Present:	Not Done _____	Comments
5.g	Symptom:	NEW OR WORSENERD JOINT PAIN	
	Symptom Present:	Not Done _____	Comments
5.h	Symptom:	CHILLS	
	Symptom Present:	Not Done _____	Comments

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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 :	Oct/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: 11281123

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

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: 11281123

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

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: 11281123

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	APPENDICITIS	Jan/15/2021 21:00	NO End Date Time: Jan/16/2021 UNK:UNK	Repeating Pages

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[APPENDICITIS]
4.	Start Date Time:	Jan/15/2021 21:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/16/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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: [APPENDICITIS]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021247541]

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

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: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

Medication Error

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

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (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: 11281123

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 Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (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: 11281123

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

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?	

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (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: 11281123

Subject Initials: ---

Generated By: pfe.levissc

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

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: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001	Form: TRANSFUSIONS
Visit: Logs - Unscheduled	Form Status: Not Started
Form Version: 22-Apr-2020 21:03	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281123	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

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: 11281123

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:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281123**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

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?	

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

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: 11281123

Subject Initials: ---

Generated By: pfe.levissc

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: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

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: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

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

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: 11281123

Subject Initials: ---

Generated By: pfe.lewissc

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

eCRF Audit Trail History

Date of Visit

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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

eCRF Audit Trail History

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/22/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001	Form: WITHDRAWAL OF CONSENT
Visit: Disposition - Unscheduled	Form Status: Not Started
Form Version: 22-Apr-2020 21:03	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281123	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

Withdrawal Of Consent		
------------------------------	--	--

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.lewissc

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

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	FOLLOW-UP
2.	Subject Status Date	Oct/16/2020

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: 11281123

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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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: 11281123

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 16:54:24 (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.

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

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](#)

Item	Date	User	Comment
Form	Aug-19-2020 12:26:16 (UTC-06:00) Central Time (US & Canada)	Dana Duvak (pfe.dduvak)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/18/2020

Form: UNPLANNED VISIT - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-12-2020 06:37:42 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: UNPLANNED 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	Oct-12-2020 06:37:42 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one Not Done

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/18/2020

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-12-2020 06:38:15 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: CONTACT OUTCOME - UNPLANNED - 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	Oct-12-2020 06:38:15 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one Not Done

Header Text: c4591001
Visit: Unplanned 1
Form Version: 22-Apr-2020 21:04
Site No: 1128
Subject No: 11281123
Generated By: pfe.levisse

Form: CONTACT OUTCOME - UNPLANNED - 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
2	Oct-12-2020 06:38:15 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: CONTACT OUTCOME - UNPLANNED - 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
3	Oct-12-2020 06:38:15 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/18/2020

Form: VITAL SIGNS - TEMP - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-12-2020 06:39:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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	Oct-12-2020 06:39:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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
2.a	Oct-12-2020 06:39:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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
2.a	Oct-12-2020 06:39:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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
2.a	Oct-12-2020 06:39:01 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - 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	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
2	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
3	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
4.a	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
4.b	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
5.a	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
5.b	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
5.c	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
5.d	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
5.e	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
5 f	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
5.g	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
5 h	Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	data is added to visit one <hr/> Not Done

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: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Mark Koch	Approved	Mar-08-2021 16:54:24 (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.

Erin McLeod	N/A	Mar-05-2021 09:12:44 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Feb-24-2021 14:02:07 (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 16:39:21 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levissc

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

Mark Koch	Approved	Jan-31-2021 11:43:09 (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.

Linda Langdon	N/A	Jan-22-2021 13:24:27 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-21-2021 11:55:51 (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-15-2021 07:40:25 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Dec-28-2020 10:54:03 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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.

Jen Vasilio	N/A	Dec-24-2020 13:45:34 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Oct-23-2020 16:20:11 (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.

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-19-2020 12:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 12:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-24-2020 04:33:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 1: Closed	Site: subject returned to complete visit the following day. consent date is correct as is.
Aug-22-2020 13:48:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	subject returned to complete visit the following day. consent date is correct as is.
Aug-22-2020 13:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Aug-19-2020 12:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: OBTAINED Date Written Consent Obtained Aug/17/2020	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

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
Aug-19-2020 12:22:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281123	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-19-2020 12:22:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1982	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-19-2020 12:23:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-19-2020 12:23:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 12:23:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: WHITE	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

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-22-2020 13:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Aug/18/2020	Transcription Error
Aug-19-2020 12:26:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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
Aug-19-2020 12:26:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-19-2020 12:26:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-19-2020 12:26:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: COMPLETED	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

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
Aug-19-2020 12:27:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Anxiety Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 12:27:13 (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
Aug-19-2020 12:27:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Anxiety	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 12:27:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: UNK/UNK/2018	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 12:27:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: YES	Initial Entry

I.b

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

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

Date	Location	User	Value	Reason
Aug-19-2020 12:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Facial Acne Start Date: Jun/UNK/2020 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 12:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 12:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Facial Acne	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 12:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Jun/UNK/2020	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 12:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-19-2020 12:27:59 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	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: 11281123

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

Time (US & Canada)			r:	
			Medical History Term:	Migraine Head aches
			Start Date:	UNK/UNK/1998
			Ongoing:	YES

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 12:27:59 (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
Aug-19-2020 12:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Migraine Headaches	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 12:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: UNK/UNK/1998	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 12:27:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-19-2020 12:28:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Headaches	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

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

			Start Date:	UNK/UNK/1990	
			Ongoing:	YES	

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 12:28:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 12:28:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Headaches	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 12:28:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: UNK/UNK/1990	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 12:28:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-19-2020 12:29:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Drug Allergy: Z-pack Start Date: UNK/UNK/2017	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

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

			Ongoing:	YES	
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I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 12:29:03 (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
Aug-19-2020 12:29:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Drug Allergy: Z-pack	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 12:29:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: UNK/UNK/2017	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 12:29:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-19-2020 12:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: History of Shingles Start Date: UNK/UNK/2006 Ongoing: YES	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

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.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 12:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 12:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: History of Shingles	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 12:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: UNK/UNK/2006	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 12:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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
Aug-22-2020 13:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-22-2020 13:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Aug/18/2020	vitals were done on 17AUG2020 and repeated on 18AUG2020 to confirm eligibility criteria
Aug-22-2020 13:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital signs Date 17/Aug/2020 is not same as Date of Visit 18/Aug/2020. Please review and update as appropriate or clarify.
Aug-19-2020 12:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-19-2020 12:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: 135.9	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 12:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: LB	Initial Entry

4. Height:

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281123

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

Date	Location	User	Value	Reason
Aug-19-2020 12:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: 61.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 12:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-19-2020 12:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-19-2020 12:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Record Identifier:: 1 Temperature: 97.0 Temperature Unit: F Temperature Loca ORAL CAV tion:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-19-2020 12:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-19-2020 12:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: 97.0	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281123

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: ---

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7.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 12:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-19-2020 12:30:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-19-2020 12:31:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-19-2020 12:31:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-24-2020 01:50:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Closed	PREGNANCY TEST date updated
Aug-22-2020 13:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-22-2020 13:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Collection Date 18/Aug/2020 is not the same as the Date of Visit 17/Aug /2020. Please correct or confirm.
Aug-22-2020 13:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-22-2020 13:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Aug/18/2020	New Information
Aug-20-2020 01:31:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Opened	[PDQ] Date of the pregnancy test 17/Aug/2020 does

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

				not the same day as the vaccination 18/Aug/2020. Please review and correct or confirm.
Aug-19-2020 12:31:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/17/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-19-2020 12:31:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-19-2020 12:31:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-19-2020 12:31:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-19-2020 12:31:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-19-2020 12:31:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-19-2020 12:31:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

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
Oct-22-2020 05:56:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 3: Closed	Response satisfies query
Oct-09-2020 07:05:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 3: Answered	per protocol at the time of randomization, the randomization could occur on a separate day of the vaccine, per our unblinded staff. Subject was listed as randomized on 17AUG2020, however did not receive injection till 18AUG2020.
Oct-07-2020 23:55:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 3: Opened	ClinQuery: Kindly update Randomization date as appropriate. Thanks.
Oct-07-2020 23:51:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 2: Deleted	ClinQuery: Kindly update Randomization date as appropriate. Thanks.
Oct-07-2020 21:07:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 2: Candidate	ClinQuery: This query is raised to unfreeze this CRF. Site wants to update randomization date.
Aug-24-2020 04:45:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 1: Closed	site: Randomization number obtained on 17AUG2020, however, subject returned the following day on

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

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

				18AUG2020 to complete vaccination visit.
Aug-22-2020 13:51:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Randomization number obtained on 17AUG2020, however, subject returned the following day on 18AUG2020 to complete vaccination visit.
Aug-22-2020 13:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Randomization Date 17/Aug/2020 is before or more than 1 day after corresponding Date of Visit 18/Aug /2020. Please review and update as appropriate.
Aug-19-2020 12:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-19-2020 12:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: 50728	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: 11281123

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-22-2020 14:00:12 (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-22-2020 14:00:12 (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-27-2020 04:49:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 2 : Closed	Per site confirmation
Aug-26-2020 13:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Query 2 : Answered	Subject had immunogenicity samples collected on 17Aug2020 and returned to clinic for vaccination on 18AUG2020.
Aug-22-2020 18:37:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2 : Opened	DMW4332108;Date of Collection is earlier or more than 1 day after Date of Visit. Please clarify or correct.
Aug-22-2020 14:01:07 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1 : Deleted	Close Auto Query

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

Central Time (US & Canada)				
Aug-22-2020 14:00:12 (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-22-2020 14:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-22-2020 14:01:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID: BK8CWZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 14:01:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BK8CWZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-22-2020 14:01:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID: BK8CX0	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: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 14:01:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> BK8CX0	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-22-2020 14:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> Sample ID: BGH7LH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 14:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> BGH7LH	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-22-2020 14:02:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> Sample ID: BGH7LJ	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 14:02:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> BGH7LJ	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-22-2020 14:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> Sample ID: BGH7LK	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.e Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 14:02:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BGH7LK	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281123**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-22-2020 14:00:18 (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-22-2020 14:00:18 (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-22-2020 14:03:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-22-2020 14:00:18 (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-22-2020 14:00:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-22-2020 14:03:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID: BGH7RR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 14:03:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BGH7RR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281123

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 12:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-19-2020 12:35:51 (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 12:35:51 (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
Oct-23-2020 03:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 1: Closed	Response satisfies query. Please close.
Oct-09-2020 07:16:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	randomization happened 17AUG2020 and injection happened 18AUG2020, PD has been reported in source and PI is aware. Does sponsor require this PD to be reported to the IRB?
Oct-08-2020 20:04:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 1: Reissued:Opened	ClinQuery: The randomization page is unfrozen. Thanks!

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1128**Subject No:** 11281123**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

Oct-07-2020 15:05:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Query 1: Answered	Please unfreeze randomization page so date can be updated.
Oct-06-2020 22:43:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 1: Reissued:Opened	ClinQuery: Please add this as PD. Randomization and dosing should happen on the same day. Thanks!
Oct-01-2020 18:32:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Query 1: Answered	Please advise if this is to be written as a protocol deviation because as per the protocol "It is anticipated that the procedures below will be conducted in a stepwise manner; however,the visit can occur over more than 1 day."
Sep-30-2020 20:35:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 1: Reissued:Opened	ClinQuery: Procedure not performed per protocol. Per protocol SOA: All steps from assessing the inclusion and exclusion criteria onwards must be conducted on the same day (including randomisation and dosing).
Sep-25-2020 12:55:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Query 1: Answered	Correct. Subject had to leave before receiving vaccine on screening day. Returned the next day for vaccine.
Sep-11-2020 02:23:44 (UTC-06:00) Central	ACV0PFEINFP6000	Rajashekhar Reddy	Query 1: Opened	ClinQuery: Randomization and

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281123

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

Time (US & Canada)		(pfe.reddy51)		dose date do not match. Please review and update, or otherwise clarify.
Sep-10-2020 18:54:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 1: Candidate	ClinQuery: Randomization and dose date do not match. Please review and update, or otherwise clarify.
Aug-19-2020 12:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: Aug/18/2020 16:17	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-19-2020 12:35:51 (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 12:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-19-2020 12:35:51 (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 12:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281123

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

administration?

Date	Location	User	Value	Reason
Aug-19-2020 12:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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
Aug-19-2020 12:35:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: NO - REACTOGENICITY E-DIARY NOT 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: 11281123

Generated By: pfe.levisc

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-29-2020 05:15:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Closed	Response satisfies query
Sep-28-2020 18:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-28-2020 18:16:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/9/2020	Initial Entry
Sep-25-2020 08:29:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 15-Sep-2020 21:54**Site No:** 1128**Subject No:** 11281123**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
Sep-28-2020 18:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-28-2020 18:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Record Identifier:: 1 Temperature: 96.5 Temperature Unit: F Temperature Locatio n:: FOREHEA D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-28-2020 18:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-29-2020 01:41:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Malla Reddy Chevella (pfe.chevem01)	Query 1: Closed	Response satisfies query
Sep-28-2020 18:19:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Query 1: Answered	per PI not of clinical significance
Sep-28-2020 18:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.5 F is outside of Normal Range 97 - 99.5 F.
Sep-28-2020 18:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 96.5	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

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

2.a Unit:

Date	Location	User	Value	Reason
Sep-28-2020 18:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-28-2020 18:17:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> FOREHEAD	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281123**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-28-2020 18:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-28-2020 18:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-28-2020 18:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/9/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-28-2020 18:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-28-2020 18:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-28-2020 18:17:44 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-28-2020 18:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-28-2020 18:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-28-2020 18:17:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-28-2020 18:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-28-2020 18:18:25 (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
Sep-28-2020 18:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-28-2020 18:18:25 (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.
Sep-28-2020 18:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-28-2020 18:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sample ID: BP9WM7	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 18:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> BP9WM7	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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
Sep-28-2020 18:20:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-28-2020 18:20:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-28-2020 18:20:09 (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
Sep-28-2020 18:20:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/9/2020 10:40	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-28-2020 18:20:09 (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
Sep-28-2020 18:20:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: LEFT	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281123

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

7. Route:

Date	Location	User	Value	Reason
Sep-28-2020 18:20:09 (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
Sep-28-2020 18:20:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-28-2020 18:20:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

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
Nov-02-2020 02:16:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 2: Closed	Per site confirmation- entered in error
Oct-30-2020 10:57:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	Site spoke with subject. Yes entry was accidental and denies any COVID-19 symptoms. Site has submitted DCF and data is corrected per TrialManager as of today.
Oct-29-2020 12:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 2: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 16Oct2020. But there is no COVID Illness visit reported in the database. Please clarify.
Oct-22-2020 01:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Closed	Closed per SITE response, Issue added to PD tracker for Clinical Review
Oct-21-2020 17:06:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	data entered is correct, visit is OOV and PD reported.
Oct-19-2020 05:30:12 (UTC-06:00) Central	ACV0PFEINFP6000	Annam Sireesha	Query 1: Opened	PDQ: DOV at this visit is out of

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

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

Time (US & Canada)		(pfe.sireea)		window (2 day) from DOV (09/Sep /2020) at V2_VAX2_L. Please reconcile and update accordingly, else confirm date is correct as is.
Oct-16-2020 09:18:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Oct/16/2020	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281123**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-16-2020 09:18:47 (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-16-2020 09:18:47 (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-16-2020 11:01:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-16-2020 09:18:47 (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-16-2020 09:18:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 11:01:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BHXNGM	Initial Entry

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: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 11:01:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BHXNGM	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-16-2020 11:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BJ6SL8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 11:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SL8	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-16-2020 11:02:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BJ6SGC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 11:02:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SGC	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.levissc

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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I. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 09:12:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Mar/5/2021	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: 11281123

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-05-2021 10:08:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-05-2021 10:08:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-05-2021 10:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 10:08:19 (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.
Mar-05-2021 10:08:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of Collection: Mar/5/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-05-2021 10:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BHPG2N	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 10:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> BHPG2N	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-05-2021 10:08:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Sample ID: BS885L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 10:08:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> BS885L	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-05-2021 10:09:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Sample ID: BS8891	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 10:09:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> BS8891	Initial Entry

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020

Form: DATE OF VISIT - 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: 11281123

Subject Initials: ---

Generated By: pfe.levissc

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 19:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Closed	Response satisfies query
Oct-10-2020 05:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 2: Deleted	Alternate query present to remove data.
Oct-09-2020 07:02:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	site has updated visit as erroneous, kindly unfreeze other pages in the visit and site can remove data and add a "not done" comment for the page.
Oct-09-2020 07:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-06-2020 01:37:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Reissued:Opened	ClinQuery:please remove the data points and update the information on page 1 under the DoV. Thanks
Oct-05-2020 18:56:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Reissued:Candidate	ClinQuery:please remove the data points and update the information on page 1 under the DoV. Thanks
Oct-02-2020 22:04:21	ACV0PFEINFP6000	Mercedes	Query 1: Answered	How does the site

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001 Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020 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: 11281123 Subject Initials: --- Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 11:25				
(UTC-06:00) Central Time (US & Canada)		Livingston (pfe.mlivingston)		capture visit as erroneous?
Oct-02-2020 13:29:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Reissued:Opened	ClinQuery: Please confirm if subject DID or DID NOT have any AE's that triggered this UNPL visit. If subject did not, please capture visit as erroneous. thanks
Oct-01-2020 19:00:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Reissued:Candidate	ClinQuery: Please confirm if subject DID or DID NOT have any AE's that triggered this UNPL visit. If subject did not, please capture visit as erroneous. thanks
Sep-30-2020 16:40:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Query 1: Answered	As per notes on contact UV page, subject was not able to stay for the vaccine and assessment time on 8/17/20 and returned on 8/18/20 for vaccine. Pre vaccine temp taken and recorded here
Sep-26-2020 19:43:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Opened	ClinQuery: Subject is listed to have a UNPL visit. Subject is not part of the reactogenicity subset. Please update the AE log to indicate why the subject had an UNPL visit. Thanks
Aug-19-2020 12:32:01	ACV0PFEINFP6000	Dana Duvak	Data Entry:	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/18/2020

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: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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(UTC-06:00) Central Time (US & Canada)		(pfe.dduvak)	Aug/18/2020	
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2. Erroneous Visit

Date	Location	User	Value	Reason
Oct-09-2020 07:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: ERRONEOUS VISIT	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.lewissc

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

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I. Assessments

Date	Location	User	Value	Reason
Oct-13-2020 19:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 5: Closed	Response satisfies query
Oct-12-2020 06:37:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Transcription Error
Oct-12-2020 06:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Oct-12-2020 00:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 5: Opened	ClinQuery: Please update this page accordingly as site has updated visit as erroneous.
Oct-11-2020 20:21:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 5: Candidate	ClinQuery: Please update this page accordingly as site has updated visit as erroneous.
Aug-27-2020 03:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 3: Closed	Response satisfies query
Aug-26-2020 13:10:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Aug-26-2020 13:04:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Aug/18/2020**Form:** UNPLANNED VISIT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281123**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

				as appropriate.
Aug-26-2020 13:04:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Initial Entry
Aug-26-2020 13:04:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: CONTACT OUTCOME	Initial Entry
Aug-25-2020 04:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 3: Opened	DM: Please review and consider to update the missing data. Thank you.
Aug-19-2020 12:34:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Aug-19-2020 12:34:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry:	Transcription Error
Aug-19-2020 12:33:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-19-2020 12:33:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: CONTACT OUTCOME	Initial Entry
Aug-19-2020 12:33:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 12:33:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry:	Transcription Error
Aug-19-2020 12:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/18/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

				as appropriate.
Aug-19-2020 12:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Dana Duvak (pfe.dduvak)	Data Entry: CONTACT OUTCOME	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

Form: CONTACT OUTCOME - UNPLANNED - 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. Contact Type:

Date	Location	User	Value	Reason
Oct-12-2020 06:38:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Aug-26-2020 13:10:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Oct-13-2020 19:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 2: Closed	Response satisfies query
Oct-12-2020 06:38:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-12-2020 06:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Oct-12-2020 00:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 2: Opened	ClinQuery: Please update this page accordingly as site has updated visit as erroneous.
Oct-11-2020 20:22:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 2: Candidate	ClinQuery: Please update this page accordingly as site has updated visit as

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Aug/18/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1128**Subject No:** 11281123**Generated By:** pfe.levisse**Form:** CONTACT OUTCOME - UNPLANNED - 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

				erroneous.
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-26-2020 13:10:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Aug-26-2020 13:10:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Contact: Aug/18/2020 Contact Outcome: VISIT ARRANGED	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Oct-12-2020 06:38:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:38:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:10:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Subject returned to clinic on 18A UG2020 to complete Visit 1 due t o their time constraints on 17AU G2020.	Initial Entry

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Aug/18/2020**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281123**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Oct-13-2020 19:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Closed	Response satisfies query
Oct-12-2020 06:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-12-2020 06:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Oct-12-2020 00:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 1: Opened	ClinQuery: Please update this page accordingly as site has updated visit as erroneous.
Oct-11-2020 20:21:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Candidate	ClinQuery: Please update this page accordingly as site has updated visit as erroneous.
Aug-26-2020 13:11:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/18/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-12-2020 06:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Record Identifier:: 1 Temperature: Not Done	Initial Entry

Header Text: c4591001
Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020
Form: VITAL SIGNS - TEMP - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51
Form Status: Data Complete, Frozen, Verified
Site No: 1128
Site Name: (1128) Ventavia Research Group
Subject No: 11281123
Subject Initials: ---
Generated By: pfe.levisse
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			Temperature Unit: Not Done Temperature Location:: Not Done	
Oct-12-2020 06:38:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Record Identifier:: 1 Temperature: Temperature Unit: Temperature Location::	Transcription Error
Oct-12-2020 06:38:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Record Identifier: 1 Temperature: Temperature Unit: Temperature Location:: ORAL CAVITY	Transcription Error
Oct-12-2020 06:38:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Record Identifier: 1 Temperature: Temperature Unit: F Temperature Location:: ORAL CAVITY	Transcription Error
Aug-26-2020 13:11:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Record Identifier: 1 Temperature: 97.3 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:				
Date	Location	User	Value	Reason
Aug-26-2020 13:11:03	ACV0PFEINFP6000	April Beech	Data Entry:	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-06:00) Central Time (US & Canada)		(pfe.abeech)	1	
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2.a Temperature:

Date	Location	User	Value	Reason
Oct-12-2020 06:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:38:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:11:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 97.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-12-2020 06:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:38:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:11:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-12-2020 06:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:38:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:11:03 (UTC-06:00) Central	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: ORAL CAVITY	Initial Entry

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
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Form: VITAL SIGNS - TEMP - 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: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)				
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Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Aug/18/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281123**Generated By:** pfe.levissc**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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 Assessment:**

Date	Location	User	Value	Reason
Oct-13-2020 19:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Closed	Response satisfies query
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-12-2020 06:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Oct-12-2020 00:29:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 1: Opened	ClinQuery: Please update this page accordingly as site has updated visit as erroneous.
Oct-11-2020 20:22:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Candidate	ClinQuery: Please update this page accordingly as site has updated visit as erroneous.
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/18/2020	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:39:15 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Aug/18/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281123**Generated By:** pfe.levisse**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - 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

Time (US & Canada)				
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:39:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: LEFT	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Reaction:: REDNESS Reaction Present:: Not Done	Initial Entry
Oct-12-2020 06:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Reaction:: REDNESS Reaction Present::	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Reaction:: REDNESS Reaction Present:: NO	Initial Entry

4.a Reaction:

Date	Location	User	Value	Reason
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: REDNESS	Initial Entry

4.a Reaction Present:

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:39:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Reaction:: SWELLING Reaction Present:: Not Done	Initial Entry
Oct-12-2020 06:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Reaction:: SWELLING Reaction Present::	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Reaction:: SWELLING Reaction Present:: NO	Initial Entry

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Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Aug/18/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281123**Generated By:** pfe.levisse**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - 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**4.b Reaction:**

Date	Location	User	Value	Reason
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: SWELLING	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: PAIN AT INJECT ION SITE Symptom Pr Not Done esent::	Initial Entry
Oct-12-2020 06:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: PAIN AT INJECT ION SITE Symptom Pr esent::	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: PAIN AT INJECT ION SITE Symptom Pr NO esent::	Initial Entry

5.a Symptom:

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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

Date	Location	User	Value	Reason
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: FATIGUE/TIRE DNESS Symptom Pre Not Done sent::	Initial Entry
Oct-12-2020 06:39:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: FATIGUE/TIRE DNESS Symptom Pre sent::	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: FATIGUE/TIRE DNESS Symptom Pre NO sent::	Initial Entry

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Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Aug/18/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281123**Generated By:** pfe.levisse**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - 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**5.b Symptom:**

Date	Location	User	Value	Reason
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: FATIGUE/TIREDNESS	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:39:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: HEADACH E Symptom Present Not Done ::	Initial Entry
Oct-12-2020 06:40:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: HEADACH E Symptom Present ::	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: HEADACH E Symptom Present NO ::	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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

5.c Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: HEADACHE	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:40:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: VOMITIN G Symptom Present: Not Done :	Initial Entry
Oct-12-2020 06:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: VOMITIN G Symptom Present: :	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: VOMITIN G Symptom Present: NO :	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Aug/18/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281123**Generated By:** pfe.levisse**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - 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**5.d Symptom:**

Date	Location	User	Value	Reason
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: VOMITING	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: DIARRHE A Symptom Present: Not Done :	Initial Entry
Oct-12-2020 06:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: DIARRHE A Symptom Present: :	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: DIARRHE A Symptom Present: NO :	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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

5.e Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: DIARRHEA	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom: NEW OR WORSEN : ED MUSCLE PAIN Symptom Not Done Present::	Initial Entry
Oct-12-2020 06:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom: NEW OR WORSEN : ED MUSCLE PAIN Symptom Present::	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom: NEW OR WORSEN : ED MUSCLE PAIN Symptom NO Present::	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Aug/18/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281123**Generated By:** pfe.levisse**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - 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**5.f Symptom:**

Date	Location	User	Value	Reason
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NEW OR WORSENERD MUSCLE PAIN	Initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom: NEW OR WORSENERD JOINT PAIN : Symptom Present:: Not Done	Initial Entry
Oct-12-2020 06:40:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom: NEW OR WORSENERD JOINT PAIN : Symptom Present::	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom: NEW OR WORSENERD JOINT PAIN : Symptom Present:: NO	Initial Entry

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Aug/18/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281123**Generated By:** pfe.levisse**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - 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**5.g Symptom:**

Date	Location	User	Value	Reason
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NEW OR WORSENEED JOINT P AIN	Initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:40:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: CHILLS Symptom Present:: Not Done	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/18/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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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5.h

Date	Location	User	Value	Reason
Oct-12-2020 06:40:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: CHILLS Symptom Present::	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Symptom:: CHILLS Symptom Present:: NO	Initial Entry

5.h Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: CHILLS	Initial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Oct-12-2020 06:41:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry
Oct-12-2020 06:40:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Aug-26-2020 13:12:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-17-2020 09:33:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Oct/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-17-2020 09:33:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-17-2020 09:33:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: COMPLETED	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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
Mar-05-2021 10:10:09 (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
Mar-05-2021 10:10:09 (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
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: APPENDICITIS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Jan/15/2021 21:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO End Date Time: Jan/16/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: 3	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-08-2021 03:22:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE APPENDICITIS: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES Is this serious event associated with congenital anomaly or bir th 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 disabil ity/incapacity?	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> APPENDICITIS	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-05-2021 10:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-08-2021 03:22:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021247541	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-24-2020 13:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/22/2020	Initial Entry

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1128**Subject No:** 11281123**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[Back to Form](#)**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Jan-25-2021 14:28:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Closed	Response satisfies query
Jan-22-2021 13:24:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-22-2021 13:24:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Participant is willing to return fo r Vaccination 3 Participant is: eligible and NOT confirmed t o have received only placebo at Vaccination 1/2	Transcription Error
Jan-19-2021 11:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Reissued:Opened	Please provide the updated source as discussed and agreed, thanks
Jan-15-2021 07:40:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-15-2021 07:40:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Participant is NOT willing to ret urn for Vaccination 3 OR otherw ise not eligible	Transcription Error
Jan-08-2021 10:08:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Opened	Per source, the subject received IP. Please update to indicate that the subject is not eligible for Vaccination 3, thanks
Dec-24-2020 13:47:44 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1128

Subject No: 11281123

Generated By: pfe.levisse

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

Time (US & Canada)				
Dec-24-2020 13:47:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-24-2020 13:47:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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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I. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-24-2021 00:32:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_36
Feb-23-2021 16:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Transcription Error
Feb-23-2021 16:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry : Dec/2 2/202 0	Transcription Error
Feb-23-2021 13:41:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (pfe.rosenr16)	Query 1: Rei ssued: Opene d	DM: Forms have been unfrozen. Please update data as necessary. Thank you.
Feb-23-2021 11:33:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: An swere d	please unfreeze crf so that site may update to 22/dec/2020
Feb-23-2021 08:38:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7352253;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levisse

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

				ADDITIONAL VACCINATION. Please review and update as appropriate.
Dec-24-2020 13:47:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry : Dec/20/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-24-2020 13:47:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281123

Generated By: pfe.lewissc

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
Oct-17-2020 09:33:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-19-2020 12:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-19-2020 12:26:40 (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
Oct-17-2020 09:33:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/16/2020	Initial Entry
Aug-19-2020 12:35:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry
Aug-19-2020 12:26:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/18/2020	Initial Entry

090177e196ae4008\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281123

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 14:31:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281138

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/18/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[11281138]
2.	Birth Date:	(b) (6)/1958
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: 11281138

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/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281138

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

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	Aug/18/2020
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: 11281138

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:	[hpv p-16 OROPHARYNGEAL cancer]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: Oct/24/2018
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diabetes mellitus II]
	Start Date:	Sep/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HPV P-16 OROPHARYNGEAL cancer]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: Oct/24/2018
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[lymph node removal]
	Start Date:	Aug/14/2018
	Ongoing:	NO End Date: Aug/14/2018

090177e196ae400c\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: 11281138

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:	[tonsillectomy]
Start Date:	Aug/14/2018
Ongoing:	NO End Date: Aug/14/2018

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

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:	Aug/18/2020
2.	Weight:	[182.9]
3.	Unit:	LB
4.	Height:	[74.0]
5.	Unit:	in
6.	Body Mass Index:	[23.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae400c\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: 11281138

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 :	Aug/18/2020
2.	Randomization Number:	[231004]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

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: Aug/18/2020
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	[BGH7MT]
5.b	Sample ID	[BGH7MV]
5.c	Sample ID	[BGH7MW]
5.d	Sample ID	[BK8CXV]
5.e	Sample ID	[BK8CXW]

090177e196ae400c\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: 11281138

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/18/2020
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	[BGH7RB]
-----	-----------	----------

090177e196ae400c\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: 11281138

Generated By: pfe.levissc

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/18/2020 16:09
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

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001	Form: REACTOGENICITY DIARY
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 06-Jul-2020 21:53	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281138	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281138

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/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281138

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:	Sep/10/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.0]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

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: Sep/10/2020
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	[BP9WMY]
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090177e196ae400c\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: 11281138

Generated By: pfe.levissc

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:	Sep/10/2020 12:21
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

090177e196ae400c\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: 11281138

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	Oct/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

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: Oct/8/2020
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	[BHXN9D]
5.b	Sample ID	[BJ6SJG]
5.c	Sample ID	[BJ6SDM]

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Illness Details

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

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

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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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: 11281138

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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1128

Subject No: 11281138

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 :	Oct/8/2020
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: 11281138

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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: 11281138

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Recurrence of Oropharyngeal Cancer, Left side	Nov/12/2020 UNK:UNK	YES	Repeating Pages

090177e196ae400c\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: 11281138

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Recurrence of Oropharyngeal Cancer, Left side]
4.	Start Date Time:	Nov/12/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? Did this serious event result in death? Did this serious event require or prolong hospitalization? Did this serious event result in persistent or significant disability/incapacity? Is this serious event life threatening? Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Cancer]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae400c\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: 11281138

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[2021046519]

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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1128

Subject No: 11281138

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	[]

090177e196ae400c\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: 11281138

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.	1	VACCINATIONS	NO	INFLUENZA VACCINE	Oct/2/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

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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Concomitant Medications

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

090177e196ae400c\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: 11281138

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.	1	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Flourouracil (5FU)	unk	Repeating Pages
2.	2	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Carboplatin	unk	Repeating Pages
3.	3	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	CISPLATIN	40	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flourouracil (5FU)]
5.	Dose:	[unk]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	Dec/17/2000
10.	Ongoing?	YES

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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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Concomitant Medications

1.	What is the medication identifier?	[2]
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Carboplatin]
5.	Dose:	[unk]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	Dec/17/2000
10.	Ongoing?	YES

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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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Concomitant Medications

1.	What is the medication identifier?	[3]	
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	
3.	Concomitant Medications Pre-specified:	NO	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[CISPLATIN]	
5.	Dose:	[40]	
6.	Dose Unit:	mg	
7.	Dose Frequency:	UNKNOWN	Comments
8.	Route:	INTRAVENOUS	
9.	Start Date:	Dec/17/2020	
10.	Ongoing?	YES	

090177e196ae400c\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: 11281138

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

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: 11281138

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: 11281138

Subject Initials: ---

Generated By: pfe.levissc

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: 11281138

Subject Initials: ---

Generated By: pfe.levissc

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?	

090177e196ae400c\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: 11281138

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: 11281138

Subject Initials: ---

Generated By: pfe.levissc

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

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

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	Jan/14/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/14/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281138

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/19/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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 - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/19/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

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

eCRF Audit Trail History

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[subject met vaccine delay criteria]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Jan/19/2021 Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT	
2.	Treatment Name	[]	
3.	Formulation:		
4.	Dose Date Time:	Not Done _____ //	Comments
5.	Anatomical Location:		
6.	Body Side:	Not Done _____	Comments
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?	Not Done _____	Comments

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281138

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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?	

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281138

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

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	FOLLOW-UP
2.	Subject Status Date	Oct/8/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281138

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
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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: 11281138

Subject Initials: ---

Generated By: pfe.levissc

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 16:55:12 (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.

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

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](#)

Item	Date	User	Comment
Form	Aug-18-2020 16:02:49 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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
7	Feb-03-2021 08:52:02 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	every week
7	Feb-02-2021 15:20:39 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	every week <hr/> Unknown
7	Feb-02-2021 15:20:06 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	every week

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-05-2021 13:42:50 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: VACCINATION - 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
4	Mar-05-2021 13:47:13 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
4	Mar-05-2021 13:46:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: VACCINATION - 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
6	Mar-05-2021 13:46:57 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: VACCINATION - 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
11	Mar-05-2021 13:47:37 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

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: 11281138

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Mark Koch	Approved	Mar-08-2021 16:55:12 (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.

Thea Sonnier	N/A	Mar-05-2021 13:42:22 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Feb-24-2021 14:03:04 (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-02-2021 15:13:42 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-31-2021 11:43:50 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae400c\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: 11281138

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-26-2021 09:51:45 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-21-2021 11:56:24 (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-16-2021 05:26:30 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Oct-23-2020 16:24:23 (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.

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281138

Generated By: pfe.levissc

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-18-2020 16:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 16:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	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: 11281138

Generated By: pfe.levissc

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
Aug-18-2020 16:02:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: OBTAINED Date Written Consent Obtained Aug/18/2020	Initial Entry

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281138

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-18-2020 16:01:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281138	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:01:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1958	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-18-2020 16:02:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-18-2020 16:02:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	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
Aug-18-2020 16:02:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: WHITE	Initial Entry

090177e196ae400c\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: 11281138

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-18-2020 16:02:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Aug/18/2020	Initial Entry

090177e196ae400c\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: 11281138

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-18-2020 16:03:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Aug/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-18-2020 16:03:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-18-2020 16:03:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: COMPLETED	Initial Entry

090177e196ae400c\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: 11281138

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

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I.a

Date	Location	User	Value	Reason
Aug-28-2020 17:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Line/MH N umber: Medical History Term: hpv p-16 OROPHA RYNGEAL cancer Start Date: UNK/UNK/2018 Ongoing: NO End Date: Oct/24/2018	New Information
Aug-18-2020 16:07:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Line/MH Number: 1 Medical History Term: hpv p-16 throat cancer Start Date: UNK/UNK/2018 Ongoing: NO End Date: Oct/24/2018	Transcription Error
Aug-18-2020 16:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: hpv p-16 throat cancer Start Date: UNK/UNK/2018 Ongoing: NO End Date: Oct/UNK/2018	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
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090177e196ae400c\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:** 11281138**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

Aug-18-2020 16:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry
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1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-28-2020 17:16:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: hpv p-16 OROPHARYNGEAL cancer	New Information
Aug-18-2020 16:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: hpv p-16 throat cancer	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2018	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:07:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO End Date: Oct/24/2018	Transcription Error
Aug-18-2020 16:04:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO End Date: Oct/UNK/2018	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-18-2020 16:05:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History Term: diabetes mellitus II	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

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

			Start Date: Sep/UNK/2018	
			Ongoing: YES	

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:05:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 16:05:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: diabetes mellitus II	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:05:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/UNK/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:05:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-28-2020 17:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Line/MH N 3 umber: Medical Hi HPV P-16 OROPH story Term ARYNGEAL cancer : Start Date: UNK/UNK/2018	New Information

090177e196ae400c\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: 11281138

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

			Ongoing: NO End Date: Oct/24/2018	
Aug-18-2020 16:07:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Line/MH Num 3 ber: Medical Histor HPV P-16 neck y Term: cancer Start Date: UNK/UNK/201 8 Ongoing: NO End Date: Oct/24/2018	Transcription Error
Aug-18-2020 16:06:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 3 ber: Medical Histor HPV P-16 neck y Term: cancer Start Date: UNK/UNK/201 8 Ongoing: NO End Date: UNK/UNK/2 018	Initial Entry

090177e196ae400c\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: 11281138

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.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:06:05 (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
Aug-31-2020 06:55:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 1: Closed	Response satisfies query
Aug-28-2020 17:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-28-2020 17:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: HPV P-16 ORO PHAR YNG EAL cancer	New Information
Aug-25-2020 09:21:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 4: Closed	duplicate
Aug-25-2020 09:21:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 1: Reissued: Opened	Please respond to this query once the action has been taken.

090177e196ae400c\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:** 11281138**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

Aug-22-2020 15:21:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: An swere d	Site has tried to contact subject for an update. left message. will up date source and edc when receive additional information
Aug-22-2020 15:21:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 4: An swere d	Site has tried to contact subject for an update. left message. will up date source and edc when receive additional information
Aug-21-2020 23:14:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 4: Op ened	Clarify HPV P-16 NECK CANCER as follows...The term is unclear. Are you reporting HPV P-16 INDUCED CERVIX UTERI CANCER? OROPHARYNGEAL CANCER? THROAT CANCER? If so, update the verbatim term as such. Otherwise clarify and edit the term. Thank you.
Aug-21-2020 23:08:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Clo sed	Discrepancy has been closed.
Aug-21-2020 22:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Op ened	Clarify HPV P-16 NECK CANCER as follows...The term is unclear. Are you reporting HPV P-16 INDUCED CERVIX UTERI CANCER? OROPHARYNGEAL CANCER? THROAT CANCER? If so, edit

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

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

				as such. Otherwise clarify and edit the term. Thank you.
Aug-21-2020 22:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.
Aug-19-2020 09:50:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Clarify HPV P-16 NECK CANCER as follows...The term is unclear. Are you reporting HPV P-16 INDUCED CERVIX UTERI CANCER? OROPHARYNGEAL CANCER? THROAT CANCER? If so, edit as such. Otherwise clarify and edit the term. Thank you.
Aug-19-2020 09:17:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify HPV P-16 NECK CANCER as follows...The term is unclear. Are you reporting HPV P-16 INDUCED CERVIX UTERI CANCER? OROPHARYNGEAL CANCER? THROAT CANCER? If so, edit as such. Otherwise clarify and edit the term. Thank you.
Aug-18-2020 16:06:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry : HPV P-16 neck cancer	Initial Entry

I.c Start Date:

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-18-2020 16:06:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2018	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:07:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO End Date: Oct/24/2018	Transcription Error
Aug-18-2020 16:06:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-18-2020 16:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: r: Medical History lymph node removal Term: Start Date: Aug/14/2018 Ongoing: NO End Date: Aug/14/2018	Initial Entry

090177e196ae400c\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: 11281138

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.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 16:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: lymph node removal	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Aug/14/2018	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO End Date: Aug/14/2018	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-18-2020 16:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: tonsillectomy Start Date: Aug/14/2018 Ongoing: NO End Date: Aug/14/2018	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: 11281138

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: ---

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1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-18-2020 16:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: tonsillectomy	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-18-2020 16:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Aug/14/2018	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-18-2020 16:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO End Date: Aug/14/2018	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281138

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
Aug-18-2020 16:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Aug/18/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-18-2020 16:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 182.9	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 16:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-18-2020 16:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 74.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 16:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-18-2020 16:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23.5	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281138

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

7.a

Date	Location	User	Value	Reason
Aug-18-2020 16:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F Temperature Location: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-18-2020 16:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-18-2020 16:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 98.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-18-2020 16:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-18-2020 16:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: FOREHEAD	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: 11281138

Generated By: pfe.levisse

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
Aug-18-2020 16:09:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Aug/18/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-18-2020 16:09:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 231004	Initial Entry

090177e196ae400c\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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 19:48:33 (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-18-2020 19:48:33 (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-18-2020 19:48:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 19:48:33 (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-18-2020 19:48:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-18-2020 19:48:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BGH7MT	Initial Entry

5.a Sample ID

090177e196ae400c\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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-18-2020 19:48:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BGH7MT	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-18-2020 19:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BGH7MV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 19:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BGH7MV	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-18-2020 19:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BGH7MW	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 19:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BGH7MW	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-18-2020 19:49:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BK8CXV	Initial Entry

090177e196ae400c\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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 19:49:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BK8CXV	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-18-2020 19:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BK8CXW	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 19:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BK8CXW	Initial Entry

090177e196ae400c\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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-18-2020 19:49:59 (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-18-2020 19:49:59 (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-18-2020 19:50:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-18-2020 19:49:59 (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-18-2020 19:49:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-18-2020 19:50:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BGH7RB	Initial Entry

5.a Sample ID

090177e196ae400c\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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-18-2020 19:50:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BGH7RB	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281138

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-18-2020 16:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-18-2020 16:10:03 (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-18-2020 16:10:03 (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-18-2020 16:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Aug/18/2020 16:09	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-18-2020 16:10:03 (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-18-2020 16:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: LEFT	Initial Entry

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

7. Route:

Date	Location	User	Value	Reason
Aug-18-2020 16:10:03 (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-18-2020 16:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-18-2020 16:10:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

090177e196ae400c\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: 11281138

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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I. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-08-2020 00:36:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Closed	Per site confirmation
Sep-05-2020 22:39:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-05-2020 22:39:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR THIS SUBJECT	Transcription Error
Sep-03-2020 02:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Premraj Bhoyar (pfe.bhoyap)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'Yes' however VAX 1 eDiary records are not available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-18-2020 16:10:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES - REACTOGENICITY E-D IARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281138

Generated By: pfe.levissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-14-2020 09:29:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/10/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1128**Subject No:** 11281138**Generated By:** pfe.levisse**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
Sep-14-2020 09:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-14-2020 09:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Record Identifier:: 1 Temperature: 97.0 Temperature Unit: F Temperature Locati on:: FOREHEA D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-14-2020 09:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-14-2020 09:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 97.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-14-2020 09:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	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: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

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

Sep-14-2020 09:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: FOREHEAD	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:** 11281138**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-16-2020 16:44:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 16:44:31 (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
Sep-16-2020 16:44:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 16:44:31 (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.
Sep-16-2020 16:44:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 16:44:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BP9WMY	Initial Entry

5.a Sample ID

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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-16-2020 16:44:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> BP9WMY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281138

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
Sep-14-2020 09:30:11 (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
Sep-14-2020 09:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-14-2020 09:30:11 (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
Sep-14-2020 09:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/10/2020 12:21	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-14-2020 09:30:11 (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
Sep-14-2020 09:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: LEFT	Initial Entry

090177e196ae400c\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: 11281138

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
Sep-14-2020 09:30:11 (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
Sep-14-2020 09:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 09:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

090177e196ae400c\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: 11281138

Generated By: pfe.levissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 11:54:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Oct/8/2020	Initial Entry

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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-08-2020 11:55:04 (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-08-2020 11:55:04 (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-08-2020 11:57:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 11:55:04 (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-08-2020 11:55:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-08-2020 11:57:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BHXN9D	Initial Entry

5.a Sample ID

090177e196ae400c\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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-08-2020 11:57:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BHXN9D	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-08-2020 11:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BJ6SJG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 11:57:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BJ6SJG	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 11:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: BJ6SDM	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 11:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: BJ6SDM	Initial Entry

090177e196ae400c\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: 11281138

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT - 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
Oct-09-2020 11:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Oct/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-09-2020 11:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-09-2020 11:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: COMPLETED	Initial Entry

090177e196ae400c\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: 11281138

Generated By: pfe.levisse

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
Jan-26-2021 09:51:45 (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: 11281138

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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
Jan-26-2021 09:51:45 (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
Jan-26-2021 09:51:45 (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
Feb-07-2021 03:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Closed	Response satisfies query
Feb-04-2021 09:43:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 2: Closed	Response satisfies query
Feb-02-2021 21:22:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	Changed data per query
Feb-02-2021 18:56:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Reissued:Opened	Thank you for confirming. Pls submit a FU form with this information so this is added to the safety report. Thanks
Feb-02-2021 15:11:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	Safety database report update sent today
Feb-02-2021 15:11:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Routine scans performed and lesion found. Biopsy done on 12NOV2020 confirmed diagnosis.

090177e196ae400c\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:** 11281138**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Jan-29-2021 12:33:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 2: Opened	SAE RECON:AE CANCER OF THE NECK(onset date:12Nov2020)was reported as serious in Safety database but reported as "Recurrence of Oropharyngeal Cancer, Left side" in CRF. Please update appropriately. If safety update is required, submit SAE form.
Jan-29-2021 09:40:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Reissued:Opened	Thank you for clarifying. Was there any reason/symptoms the subject had that prompted the biopsy on 12Nov2020?
Jan-26-2021 13:57:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-26-2021 13:57:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Recurrence of Oropharyngeal C ancer, Left side	New Information
Jan-26-2021 11:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Opened	CLINICAL_ Pls clarify the clinical presentation and if this event was a recurrence. Thanks
Jan-26-2021 09:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Neck Cancer, Left side	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-26-2021 09:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/12/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

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

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jan-26-2021 09:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 09:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-29-2021 12:29:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 14:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query
Jan-26-2021 13:57:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Recurrence of Oropharyngeal Cancer, Left side: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-26-2021 09:53:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

090177e196ae400c\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:** 11281138**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Jan-26-2021 09:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Jan-26-2021 09:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Neck Cancer, Left side: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-26-2021 09:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Other medically important serio us event YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-26-2021 09:51:45 (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
Jan-26-2021 09:51:45 (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 If Other, specify: Cancer	Initial Entry

10. Latest Action Taken with Study Treatment:

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281138**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Jan-26-2021 09:51:45 (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
Jan-26-2021 09:51:45 (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
Jan-26-2021 09:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-26-2021 09:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-26-2021 09:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-29-2021 12:29:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Data Entry: 2021046519	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Oct-12-2020 14:40:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-12-2020 14:40:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-12-2020 14:40:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-12-2020 14:40:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-12-2020 14:40:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: INFLUENZA VACCINE	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-12-2020 14:40:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Oct/2/2020	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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
Feb-02-2021 15:13:42 (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 21:03

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-02-2021 15:15:55 (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 21:03

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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
Feb-02-2021 15:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-02-2021 15:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-02-2021 15:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: CONCOMITANT IMMUNOSUP PRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-02-2021 15:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-02-2021 15:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Flourouracil (5FU)	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Feb-02-2021 15:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: unk	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
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090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Feb-02-2021 15:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: mg	Initial Entry
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7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-02-2021 15:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Feb-02-2021 15:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Feb-02-2021 15:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Dec/17/2000	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-02-2021 15:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-02-2021 15:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-02-2021 15:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> CONCOMITANT IMMUNOSUP PRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-02-2021 15:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-02-2021 15:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Carboplatin	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Feb-02-2021 15:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> unk	Initial Entry

6. Dose Unit:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

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Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Feb-02-2021 15:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-02-2021 15:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Feb-02-2021 15:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Feb-02-2021 15:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Dec/17/2000	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-02-2021 15:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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: 11281138

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Generated By: pfe.levisse

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-02-2021 15:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-02-2021 15:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> CONCOMITANT IMMUNOSUP PRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-02-2021 15:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-02-2021 23:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Feb-02-2021 22:26:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-02-2021 22:26:04	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> CISPLATIN	Transcription Error

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281138**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)				
Feb-02-2021 19:30:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify CISTOPLATIN as follows...Should the spelling be CISPLATIN? If so, edit. Otherwise clarify or provide reference/label. Thank you.
Feb-02-2021 15:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Cistoplatin	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Feb-02-2021 15:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 40	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-02-2021 15:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-03-2021 14:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe.francm73)	Query 1: Closed	Response satisfies query
Feb-03-2021 08:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: UNKNOWN	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281138**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Feb-03-2021 08:52:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Every week is not available in the dropdown list
Feb-03-2021 08:52:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Feb-03-2021 01:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Opened	DM: Per comment "every week", please review and select appropriate dose frequency from dropdown list. Thank you.
Feb-02-2021 15:20:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Unknown	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Feb-02-2021 15:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Feb-02-2021 15:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Dec/17/2020	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-02-2021 15:19:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-16-2021 05:26:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Jan/14/2021	Initial Entry

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1128**Subject No:** 11281138**Generated By:** pfe.levisse**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)***1. Select appropriate response - Is participant willing to return for Vaccination 3?***

Date	Location	User	Value	Reason
Mar-09-2021 06:18:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Deepthi Chandrasekaran (pfe.chandd38)	Query 2: Closed	Response satisfies query
Mar-08-2021 19:49:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	subject is a vaccine delay
Mar-03-2021 20:48:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 2: Opened	DM: Participant is eligible and confirmed to have received Placebo on the Further Vaccination Confirmation CRF, However Date Written Consent Obtained is missing in Informed Consent - Further Vaccination CRF. Kindly review and update, else clarify.
Jan-16-2021 05:27:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-16-2021 05:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-16-2021 05:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Participant is willing to return fo r Vaccination 3 Participant is:	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281138

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-16-2021 05:27:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Jan/14/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-16-2021 05:27:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: ASSESS ELIGIBILITY FOR ADD ITIONAL VACCINATION	Initial Entry

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281138

Generated By: pfe.levissc

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
Mar-05-2021 13:42:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Jan/19/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Consent Was:

Date	Location	User	Value	Reason
Mar-05-2021 13:42:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: OBTAINED Date Written Consent Obtained Jan/19/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

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
Mar-05-2021 13:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Jan/19/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-05-2021 13:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-05-2021 13:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: COMPLETED	Initial Entry

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-05-2021 13:43:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-05-2021 13:43:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-05-2021 13:45:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-05-2021 13:45:26 (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 provide reason' is missing. Please review and update as appropriate.
Mar-05-2021 13:45:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 13:45:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Transcription Error
Mar-05-2021 13:43:25 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)				barcodes are entered. Please review and correct as appropriate.
Mar-05-2021 13:43:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of Collection: Jan/19/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-05-2021 13:45:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: subject meets vaccine delay	Initial Entry

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-05-2021 13:46:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-05-2021 13:46:24 (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
Mar-05-2021 13:46:24 (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
Mar-05-2021 13:46:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: subject met vaccine delay criteria	Initial Entry

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281138

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-05-2021 13:44:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of First Delay: Jan/19/2021 Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-05-2021 13:47:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Mar-05-2021 13:46:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-05-2021 13:46:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Mar-05-2021 13:47:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry

090177e196ae400c\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281138**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
Feb-02-2021 18:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Closed	Update noted. Thanks
Feb-02-2021 17:49:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	Query is not clear as AE 1 is already recorded.
Jan-24-2021 08:54:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Opened	CLINICAL_ AER#2021046519. If the subject will be receiving treatment with chemotherapy, per CRF CG V11, section 8.53., details of prohibited medications should be recorded on CRF. Kindly reassess and update the PROHIB CM accordingly. Thank you.
Oct-09-2020 11:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-18-2020 16:09:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-18-2020 16:03:20 (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
Feb-04-2021 11:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Closed	SAE entered on Log form

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281138

Subject Initials: ---

Generated By: pfe.levisse

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

Feb-02-2021 17:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	Query is not clear as prohibited conmed is already recorded.
Jan-21-2021 04:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2021046519 cancer of the neck(onset date:12Nov2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-09-2020 11:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/8/2020	Initial Entry
Aug-18-2020 16:09:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/18/2020	Initial Entry
Aug-18-2020 16:03:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/18/2020	Initial Entry

090177e196ae400c\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: 11281138

Generated By: pfe.levissc

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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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 13:13:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281153

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

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/19/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: DEMOGRAPHY

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](#)

Demography		
1.	Subject ID	[11281153]
2.	Birth Date:	(b) (6)/1979
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

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: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281153

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae4011\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: 11281153

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	Aug/19/2020
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: 11281153

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:	[Attention deficit disorder]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[depression]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bipolar depression disorder type 3]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[general myalgia]
	Start Date:	UNK/UNK/1992
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[insomnia]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES

090177e196ae4011\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: 11281153

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.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[drug allergy: demerol]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[stargardt's disease, both eyes]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Appendicitis]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: UNK/UNK/2002
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Appendectomy]
	Start Date:	UNK/UNK/2002
	Ongoing:	NO End Date: UNK/UNK/2002

090177e196ae4011\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: 11281153

Generated By: pfe.levisse

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:	Aug/19/2020
2.	Weight:	[154.0]
3.	Unit:	LB
4.	Height:	[65.0]
5.	Unit:	in
6.	Body Mass Index:	[25.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[96.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae4011\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: 11281153

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

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

Lab Result

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

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 :	Aug/19/2020
2.	Randomization Number:	[57612]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

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: 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	[BGH7P9]
5.b	Sample ID	[BGH7PB]
5.c	Sample ID	[BGH7PC]
5.d	Sample ID	[BK8CYV]
5.e	Sample ID	[BK8CYW]

090177e196ae4011\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: 11281153

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	[BP9W9Y]
-----	-----------	----------

090177e196ae4011\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: 11281153

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 17:39
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

090177e196ae4011\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: 11281153

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

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/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281153

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:	Sep/9/2020	Comments
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Vital Signs Details

2.a	Record Identifier:	1	
	Temperature:	[97.3]	Comments
	Unit:	F	Comments
	Temperature Location:	FOREHEAD	Comments

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/9/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

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: Sep/9/2020
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	[BP9WMV]
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090177e196ae4011\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: 11281153

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:	Sep/9/2020 17:06
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

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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	Oct/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

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: Oct/14/2020
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	[BJ6SFP]
5.b	Sample ID	[BJ6SKJ]
5.c	Sample ID	[BHXNFY]

090177e196ae4011\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/04/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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/4/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/4/2020
2.	Date of First Symptom Started:	Nov/3/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/8/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	YES
4.d	Symptoms:	CHILLS
	Was symptom present?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

090177e196ae4011\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/04/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Symptoms - Other Text:

[NAUSEA]

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: 11281153

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.	Nov/8/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Nov/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Nov/8/2020	Comments
2.	Specimen Type:	SWABBED MATERIAL	Comments
3.	Specimen Collection Location:	NASOPHARYNX	Comments
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Comments
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	Comments
6.	Trade Name:	OTHER	Comments
7.	Test Result:	NEGATIVE	Comments
8.	Comments/Findings/Details:	[]	Comments
9.	Trade Name Other, Specify:	[NALT UNKNOWN]	Comments

090177e196ae4011\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/04/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Nov/4/2020
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	[CV02845]
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090177e196ae4011\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/04/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[SUBJECT COMPLETED HOME NASAL SWAB. SITE NASAL SWAB NOT EXPECTED]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[]
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090177e196ae4011\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/04/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**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:	NO	Comments
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM	
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]	Comments
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN	
	Occurrence of Visits or Contacts:	NO	Comments
1.d	Physician or Healthcare Professional:	URGENT CARE	
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]	Comments
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION	
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [2]	Comments
1.f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	NO	Comments

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]	Comments
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Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO	Comments
----	--	----	--------------------------

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: 11281153

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

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Nov/04/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Nov/04/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [sepsis] Date of Diagnosis: Nov/8/2020
3.	Toxicity Grade:	1

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

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: 11281153

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/04/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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: 11281153

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/04/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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

090177e196ae4011\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: 11281153

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/04/2020

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae4011\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: 11281153

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/04/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 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: 11281153

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/04/2020

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Vital Signs

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

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: 11281153

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/04/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Oxygenation Parameters

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

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

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: 11281153

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/04/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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?	

090177e196ae4011\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: 11281153

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/04/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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 1 - Unscheduled
Visit on Dec/07/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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	Dec/7/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/07/2020

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: 11281153

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: Dec/7/2020
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	[BJ6SZ9]
5.b	Sample ID	[BS7NGT]
5.c	Sample ID	[BHXN66]

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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/14/2020
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: 11281153

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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: 11281153

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 Ongoing	Form Instance
1.	ADVERSE EVENT	1	Thrombocytopenia	Nov/4/2020 UNK:UNK	NO End Date Time: Nov/13/2020 UNK:UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	HEADACHE	Nov/5/2020 16:00	NO End Date Time: Nov/11/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Hepatocellular injury	Nov/4/2020 UNK:UNK	NO End Date Time: Nov/13/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	VIRAL SYNDROME	Nov/4/2020 UNK:UNK	NO End Date Time: Nov/13/2020 UNK:UNK	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Thrombocytopenia]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/13/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Hepatocellular injury]

090177e196ae4011\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: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

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?:	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	[2020457282]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Incomplete, Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[HEADACHE]
4.	Start Date Time:	Nov/5/2020 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/11/2020 UNK:UNK
6.	Toxicity Grade:	
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Incomplete, Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

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	[]

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281153**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hepatocellular injury]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/13/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [VIRAL SYNDROME]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020457282]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[VIRAL SYNDROME]
4.	Start Date Time:	Nov/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/13/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [virus]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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: 11281153

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: 11281153

Generated By: pfe.levisse

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	[]

090177e196ae4011\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: 11281153

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.	1	VACCINATIONS	NO	INFLUENZA VACCINE	Nov/12/2020	Repeating Pages

090177e196ae4011\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: 11281153

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

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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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[INFLUENZA VACCINE]
5.	Date:	Nov/12/2020

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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: 11281153

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

090177e196ae4011\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: 11281153

Generated By: pfe.levisse

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?	

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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: 11281153

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

090177e196ae4011\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: 11281153

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae4011\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: 11281153

Generated By: pfe.levisse

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: 11281153

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: 11281153

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: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

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: 11281153

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?	

090177e196ae4011\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: 11281153

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: 11281153

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: 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: 11281153

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	Jan/19/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

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

[eCRF Audit Trail History](#)

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/25/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/25/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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 - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/25/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/25/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPGG3]
5.b	Sample ID	[BS87Z8]
5.c	Sample ID	[BS883K]

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/25/2021 16:02
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/24/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/24/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/24/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/24/2021 16:45
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

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	FOLLOW-UP
2.	Subject Status Date	Oct/14/2020

090177e196ae4011\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: 11281153

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: 11281153

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-10-2021 14:58:40 (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.

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

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](#)

Item	Date	User	Comment
Form	Aug-19-2020 18:59:27 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

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](#)

Item	Date	User	Comment
1	Sep-23-2020 20:52:11 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1	Aug-28-2020 10:04:49 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Visit 2 has not been performed yet for this subject. Unknown

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

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](#)

Item	Date	User	Comment
2.a	Sep-23-2020 20:53:06 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
2.a	Aug-28-2020 10:05:27 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Visit 2 has not been performed for this subject yet. Unknown

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

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](#)

Item	Date	User	Comment
2.a	Sep-23-2020 20:54:58 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
2.a	Aug-28-2020 10:05:27 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Visit 2 has not been performed for this subject yet. Unknown

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

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](#)

Item	Date	User	Comment
2.a	Sep-23-2020 20:55:28 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
2.a	Aug-28-2020 10:05:27 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Visit 2 has not been performed for this subject yet. Unknown

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
Form	Nov-05-2020 10:25:30 (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/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
1	Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1	Nov-05-2020 10:25:30 (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/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
2	Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
2	Nov-05-2020 10:25:30 (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/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
3	Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
3	Nov-05-2020 10:25:30 (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/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
4	Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
4	Nov-05-2020 10:25:30 (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/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
5	Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
5	Nov-05-2020 10:25:30 (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/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
6	Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
6	Nov-05-2020 10:25:30 (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/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
7	Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
7	Nov-05-2020 10:25:30 (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/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
8	Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
8	Nov-05-2020 10:25:30 (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/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
9	Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
9	Nov-05-2020 10:25:30 (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/04/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
Form	Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Not Complete

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	Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1.a	Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Not Complete

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	Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1.b	Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Not Complete

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	Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1.c	Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Not Complete

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	Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1.d	Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Not Complete

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	Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1.e	Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Not Complete

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	Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
1 f	Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Not Complete

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	Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
2	Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 15:59

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Frozen, Not Complete

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	Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
3	Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Jan-25-2021 17:50:21 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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-10-2021 14:58:40 (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.

Thea Sonnier	N/A	Mar-09-2021 10:41:48 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Mar-08-2021 16:58:33 (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.

Erin McLeod	N/A	Feb-24-2021 16:08:52 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Feb-24-2021 14:04:02 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae4011\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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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	Feb-23-2021 12:25:23 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-31-2021 11:45:00 (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	Jan-25-2021 11:09:14 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-21-2021 11:57:22 (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.

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

090177e196ae4011\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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Jen Vasilio	N/A	Dec-29-2020 18:13:11 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Mark Koch	Approved	Dec-28-2020 10:54:42 (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.

Thea Sonnier	N/A	Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Mark Koch	Approved	Dec-11-2020 10:12:54 (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.

Reyna Gomez	N/A	Dec-07-2020 11:38:17 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Mark Koch	Approved	Dec-02-2020 19:37:45 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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.

Ricell Ann Piojo	N/A	Nov-19-2020 05:01:33 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Nov-18-2020 16:38:17 (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	Nov-18-2020 11:03:22 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Nov-14-2020 12:28:51 (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.

090177e196ae4011\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:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Thea Sonnier	N/A	Nov-09-2020 14:21:35 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Mark Koch	Approved	Nov-06-2020 12:20:00 (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.				
Thea Sonnier	N/A	Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Mark Koch	Approved	Nov-05-2020 12:06:22 (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.				
Erin McLeod	N/A	Nov-05-2020 09:39:16 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Mark Koch	Approved	Oct-23-2020 16:27:08 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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: 11281153

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
Aug-19-2020 18:58:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 18:58:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

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
Aug-19-2020 18:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: OBTAINED Date Written Consent Obtained Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281153

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
Aug-19-2020 18:58:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281153	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-19-2020 18:58:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1979	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-19-2020 18:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-19-2020 18:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	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
Aug-19-2020 18:59:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: WHITE	Initial Entry

090177e196ae4011\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: 11281153

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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1. Date of Visit

Date	Location	User	Value	Reason
Aug-19-2020 18:59:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

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
Aug-19-2020 18:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-19-2020 18:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-19-2020 18:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: COMPLETED	Initial Entry

090177e196ae4011\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: 11281153

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
Aug-19-2020 19:01:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: er: Medical History Attention deficit disorder Term: Start Date: UNK/UNK/2008 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:01:15 (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
Aug-19-2020 19:01:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Attention deficit disorder	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:01:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2008	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 19:01:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
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090177e196ae4011\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: 11281153

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

Aug-19-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: depression Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry
---	-----------------	-------------------------	---	---------------

I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:01:48 (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-19-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: depression	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1995	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 19:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-19-2020 19:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: bipolar depression disorder type 3	Initial Entry

090177e196ae4011\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: 11281153

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

			Start Date: UNK/UNK/2005	
			Ongoing: YES	

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:02:32 (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
Aug-19-2020 19:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: bipolar depression disorder type 3	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2005	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 19:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-19-2020 19:03:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: general myalgia Start Date: UNK/UNK/1992 Ongoing: YES	Initial Entry

090177e196ae4011\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: 11281153

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.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:03:32 (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
Aug-19-2020 19:03:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: general myalgia	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:03:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1992	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 19:03:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-19-2020 19:04:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: insomnia Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

090177e196ae4011\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: 11281153

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.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:04:08 (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
Aug-19-2020 19:04:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: insomnia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:04:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2014	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 19:04:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-19-2020 19:04:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: drug allergy: demerol Start Date: UNK/UNK/2002 Ongoing: YES	Initial Entry

090177e196ae4011\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: 11281153

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.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:04:42 (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
Aug-19-2020 19:04:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: drug allergy: demerol	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:04:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2002	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 19:04:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-19-2020 19:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 7 ber: Medical Histor stargardt's disease, y Term: both eyes Start Date: UNK/UNK/1998 Ongoing: YES	Initial Entry

090177e196ae4011\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: 11281153

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.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:06:22 (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
Aug-19-2020 19:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: stargardt's disease, both eyes	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1998	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 19:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-19-2020 19:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 8 : Medical History T Appendicitis erm: Start Date: UNK/UNK/200 2 Ongoing: NO End Date: UNK/UNK/2 002	Initial Entry

090177e196ae4011\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: 11281153

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.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 19:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Appendicitis	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2002	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 19:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO End Date: UNK/UNK/2002	Initial Entry

I.i

Date	Location	User	Value	Reason
Aug-19-2020 19:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 9 : Medical History T Appendectomy erm: Start Date: UNK/UNK/2002 Ongoing: NO End Date: UNK/UNK/2002	Initial Entry

090177e196ae4011\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: 11281153

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

L.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 19:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> Appendectomy	Initial Entry

L.i Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> UNK/UNK/2002	Initial Entry

L.i Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 19:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> NO End Date: UNK/UNK/2002	Initial Entry

090177e196ae4011\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: 11281153

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
Aug-19-2020 19:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/19/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-19-2020 19:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 154.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 19:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-19-2020 19:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 65.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 19:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-19-2020 19:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.6	Initial Entry

090177e196ae4011\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: 11281153

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

7.a

Date	Location	User	Value	Reason
Aug-19-2020 19:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Record Identifier:: 1 Temperature: 96.5 Temperature Unit: F Temperature Locati on:: ORAL CAVI TY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-19-2020 19:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-20-2020 16:44:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Closed	Response satisfies query
Aug-20-2020 12:08:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Query 1: Answered	NCS
Aug-20-2020 04:48:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 1: Reissued:Opened	DM query: Kindly confirm if the temp is clinically significant or not. If clinically significant, report an AE accordingly on the AE page. Thank you.
Aug-19-2020 19:10:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Query 1: Answered	Original value is correct
Aug-19-2020 19:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.5 F is outside of Normal Range 97 - 99.5 F.
Aug-19-2020 19:09:26 (UTC-06:00) Central	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 96.5	Initial Entry

090177e196ae4011\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: 11281153

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

Time (US & Canada)				
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7.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 19:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-19-2020 19:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-19-2020 19:10:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-19-2020 19:10:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-19-2020 19:10:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> Aug/19/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-19-2020 19:10:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-19-2020 19:10:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-19-2020 19:10:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

			Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	
--	--	--	--	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-19-2020 19:10:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-19-2020 19:10:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-19-2020 19:10:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4011\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: 11281153

Generated By: pfe.levisse

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
Aug-19-2020 19:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/19/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-19-2020 19:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 57612	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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 19:11:52 (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 19:11:52 (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-19-2020 19:13:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 19:11:52 (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 19:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 19:13:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID: BGH7P9	Initial Entry

5.a Sample ID

090177e196ae4011\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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-19-2020 19:13:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> BGH7P9	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-19-2020 19:14:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> Sample ID: BGH7PB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 19:14:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> BGH7PB	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-19-2020 19:14:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> Sample ID: BGH7PC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 19:14:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> BGH7PC	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-19-2020 19:15:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> Sample ID: BK8CYV	Initial Entry

090177e196ae4011\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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 19:15:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BK8CYV	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-19-2020 19:15:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID: BK8CYW	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 19:15:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BK8CYW	Initial Entry

090177e196ae4011\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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 19:11:59 (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 19:11:59 (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 19:17:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 19:11:59 (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 19:11:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 19:17:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID: BP9W9Y	Initial Entry

5.a Sample ID

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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: 11281153

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Aug-19-2020 19:17:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> BP9W9Y	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: 11281153

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 19:12:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-19-2020 19:12:28 (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 19:12:28 (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 19:12:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/19/2020 17:39	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-19-2020 19:12:28 (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 19:12:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: LEFT	Initial Entry

090177e196ae4011\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: 11281153

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

7. Route:

Date	Location	User	Value	Reason
Aug-19-2020 19:12:28 (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 19:12:28 (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 19:12:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

090177e196ae4011\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: 11281153

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
Aug-19-2020 19:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO - REACTOGENICITY E-DIARY NOT 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: 11281153

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-15-2020 15:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/9/2020	Transcription Error
Sep-15-2020 15:39:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Aug-31-2020 01:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 4: Closed	Per site confirmation
Aug-31-2020 00:13:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 5: Opened	DM: Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Aug-28-2020 10:04:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Query 4: Answered	Visit 2 has not been performed yet.
Aug-28-2020 10:03:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Aug-27-2020 09:01:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 2: Closed	Closed as per site confirmation
Aug-27-2020 04:08:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 4: Opened	DM: As per CRF completion guidelines section 8.4.2, if visit date was entered in error, tick the radio button to indicate that the visit entry is

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Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281153**Generated By:** pfe.levissc**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

				erroneous. Please check and update accordingly.
Aug-27-2020 03:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 3: Closed	per site confirmation
Aug-26-2020 15:53:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Query 3: Answered	Information was inadvertently entered under Visit 2 CRF instead of the intended Visit 1 CRF. Subject has not been into clinic for their scheduled Visit 2 yet.
Aug-26-2020 15:53:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Query 2: Answered	Information was inadvertently entered under Visit 2 CRF instead of the intended Visit 1 CRF. Subject has not been into clinic for their scheduled Visit 2 yet.
Aug-25-2020 08:30:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Aanchal Asthana (pfe.asthaa03)	Query 3: Opened	DM: The form LAB PREG, SWAB PFE, VACIN TRT are missing. Kindly update.
Aug-24-2020 08:07:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 2: Opened	PDQ: Date of visit at this visit is out of window (-18 day) from Date of visit (19/Aug/2020) at VID1VX1L visit. Please reconcile and update accordingly, else confirm date is correct as is.
Aug-22-2020 15:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-21-2020 01:47:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Opened	DM: Erroneous Visit is marked, but date of visit is entered. Please check whether

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

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

				other assessments are performed at this visit.
Aug-20-2020 13:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Aug-20-2020 12:58:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/20/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Sep-15-2020 15:39:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry:	Transcription Error
Aug-28-2020 10:03:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: ERRONEOUS VISIT	Initial Entry
Aug-22-2020 15:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Transcription Error
Aug-20-2020 13:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: ERRONEOUS VISIT	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

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

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I. Date:

Date	Location	User	Value	Reason
Sep-24-2020 06:51:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 2: Closed	data updated
Sep-23-2020 20:52:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Sep-23-2020 20:52:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sep/9/2020	Initial Entry
Sep-23-2020 20:52:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Sep-23-2020 06:38:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 2: Reissued:Opened	PDQ RQ2 : V2_VAX2_L:VITAL SIGNS - TEMP form has already been unfrozen , please update as per the below query.
Sep-22-2020 14:04:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	the CRF is not unfrozen for the site. the date is still frozen. Please unfreeze CRF
Sep-22-2020 00:45:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 2: Reissued:Opened	PDQ RQ1 : Thank you for the response, the form has been unfrozen now, please update as per the below query.
Sep-21-2020 19:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	Please unfreeze CRF so that site may enter data
Sep-17-2020 02:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 2: Opened	PDQ :As per response to previous queries, Visit 2 has been occurred on 9Sep20, hence it is expected to

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Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:28**Site No:** 1128**Subject No:** 11281153**Generated By:** pfe.levisse**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

				update the Vital signs details for this subject else clarify.
Aug-28-2020 10:04:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Unknown	Initial Entry
Aug-27-2020 03:57:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Closed	per site confirmation
Aug-26-2020 15:53:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Query 1: Answered	Information was inadvertently entered under Visit 2 CRF instead of the intended Visit 1 CRF. Subject has not been into clinic for their scheduled Visit 2 yet.
Aug-25-2020 10:05:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Opened	DM: Please review and update the missing data. Thank you.
Aug-20-2020 13:03:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry:	Transcription Error
Aug-20-2020 12:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/20/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-23-2020 20:55:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Record Identifier:: 1 Temperature: 97.3 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry
Sep-23-2020 20:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Record Identifier:: 1 Temperature: 97.3 Temperature Unit: F Temperature Location::	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:28**Site No:** 1128**Subject No:** 11281153**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

Sep-23-2020 20:55:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Record Identifier:: 1 Temperature: 97.3 Temperature Unit: F Temperature Location :: Unknow n	Initial Entry
Sep-23-2020 20:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Record Identifier:: 1 Temperature: 97.3 Temperature Unit: Temperature Location :: Unknow n	Initial Entry
Sep-23-2020 20:53:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Record Identifier:: 1 Temperature: 97.3 Temperature Unit: Unknow n Temperature Location :: Unknow n	Initial Entry
Sep-23-2020 20:53:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Record Identifier:: 1 Temperature: Temperature Unit: Unknow n Temperature Location :: Unknow n	Initial Entry
Aug-28-2020 10:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Record Identifier:: 1 Temperature: Unknow n Temperature Unit: Unknow n Temperature Location :: Unknow n	Initial Entry
Aug-22-2020 15:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Record Identifier:: 1 Temperature: Temperature Unit: Temperature Location::	Transcription Error

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:28**Site No:** 1128**Subject No:** 11281153**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-22-2020 15:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Record Identifier:: 1 Temperature: Temperature Unit: F Temperature Location::	Transcription Error
Aug-20-2020 13:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Record Identifier:: 1 Temperature: Temperature Unit: F Temperature Location: FOREHEAD	New Information
Aug-20-2020 13:01:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Record Identifier:: 1 Temperature: 97.2 Temperature Unit: F Temperature Location: FOREHEAD	Initial Entry
Aug-20-2020 12:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Record Identifier:: 1 Temperature: Temperature Unit: Temperature Location::	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-20-2020 12:58:55 (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
Sep-23-2020 20:53:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 97.3	Initial Entry
Sep-23-2020 20:53:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Aug-28-2020 10:05:27	ACV0PFEINFP6000	April Beech	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281153

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

(UTC-06:00) Central Time (US & Canada)		(pfe.abeech)	Unknown	
Aug-20-2020 13:04:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry:	New Information
Aug-20-2020 13:01:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 97.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-23-2020 20:55:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: F	Initial Entry
Sep-23-2020 20:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Aug-28-2020 10:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Unknown	Initial Entry
Aug-22-2020 15:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Transcription Error
Aug-20-2020 13:01:27 (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
Sep-23-2020 20:55:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: FOREHEAD	Initial Entry
Sep-23-2020 20:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Aug-28-2020 10:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Unknown	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

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Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

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-22-2020 15:45:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Transcription Error
Aug-20-2020 13:01:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: FOREHEAD	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-15-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-15-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-15-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/9/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-15-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-15-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-15-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

			Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	
--	--	--	--	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-15-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-15-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-15-2020 15:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NEGATIVE	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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-15-2020 15:53:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-15-2020 15:53:03 (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
Sep-15-2020 15:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-15-2020 15:53:03 (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.
Sep-15-2020 15:53:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-15-2020 15:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BP9WMV	Initial Entry

5.a Sample ID

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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: 11281153

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Sep-15-2020 15:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> BP9WMV	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281153

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
Sep-15-2020 15:40:59 (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
Sep-15-2020 15:40:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-15-2020 15:40:59 (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
Sep-15-2020 15:40:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/9/2020 17:06	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-15-2020 15:40:59 (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
Sep-15-2020 15:40:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: LEFT	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281153

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

7. Route:

Date	Location	User	Value	Reason
Sep-15-2020 15:40:59 (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
Sep-15-2020 15:40:59 (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
Sep-15-2020 15:40:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

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
Oct-17-2020 02:45:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Praful Prabhakar (pfe.prabhp12)	Query 1: Closed	Response satisfies query
Oct-16-2020 05:00:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	updated
Oct-16-2020 04:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Patient completed the treatment phase and reached at Visit 3. Kindly consider to update EOT form with matching V3 date or else clarify. Thank you.
Oct-14-2020 09:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Oct/14/2020	Initial Entry

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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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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1. Data Origin

Date	Location	User	Value	Reason
Oct-14-2020 11:35:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-14-2020 11:35:43 (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-14-2020 11:36:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 11:35:43 (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-14-2020 11:35:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-14-2020 11:36:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BJ6SFP	Initial Entry

5.a Sample ID

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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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-14-2020 11:36:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SFP	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 11:36:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BJ6SKJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 11:36:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SKJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 11:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BHXNfy	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 11:36:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BHXNfy	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Nov/04/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**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
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-05-2020 09:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 09:39:15 (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.
Nov-05-2020 09:39:15 (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.
Nov-05-2020 09:39:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Nov/4/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-05-2020 09:39:15 (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/04/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/4/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/3/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 05:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Feb-23-2021 12:25:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-23-2021 12:25:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO Date of Last Symptom Resolved: Nov/8/2020	New Information
Feb-17-2021 09:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 1: Reissued:Opened	Please confirm the symptoms are still ongoing for this COVID Illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else clarify.
Feb-03-2021 12:49:02 (UTC-06:00) Central	ACV0PFEINFP6000	Behnaz Yousefzadeh-	Query 1: Reissued:Candidate	site to clarify stop dates with subject

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Time (US & Canada)		Khiabani (pfe.youseb01)		and update as appropriate
Feb-02-2021 21:09:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	site to clarify stop dates with subject and update as appropriate
Feb-02-2021 03:57:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Devi Subhash (pfe.subhaa)	Query 1: Opened	Please confirm the symptoms are still ongoing for this COVID Illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else clarify.
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: FEVER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (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
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.b

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (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
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (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

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**4.c Symptoms:**

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (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
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (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
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms NEW OR INCREASED MUSCLE PAIN : Symptom YES Present:	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**4.e Symptoms:**

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (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
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW LOSS OF TAS TE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (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
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms NEW OR INCREASE : D SORE THROAT	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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			Symptom NO Present:	
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4.g Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (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
Nov-05-2020 10:24:17 (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
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: VOMITING	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)			Symptom Present: NO	
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4.i Symptoms:

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-05-2020 10:24:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 10:24:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Symptoms - Other: NAUSEA	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-05-2020 10:24:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NAUSEA	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
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Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Dec-15-2020 16:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Nov/04/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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I. Actual Date of Collection:

Date	Location	User	Value	Reason
Dec-23-2020 01:34:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Closed	Response satisfies query
Dec-22-2020 11:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-22-2020 11:12:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/8/2020	Changed Information
Dec-16-2020 09:26:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Reissued:Opened	Clin: It was stated in the SAE report #2020457282 of VIRAL PNEUMONIA that the subject has a NEGATIVE SARS-CoV-2 NAAT test result on 08Nov2020. Please capture this information on the MICROBIOLOGY SPECIMEN CRF form
Dec-15-2020 16:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-15-2020 16:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/5/2020	Initial Entry
Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Dec-14-2020 10:45:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: It was stated in the SAE report #2020457282 of VIRAL PNEUMONIA that

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
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Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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				the subject has a NEGATIVE SARS-CoV-2 NAAT test result on 05Nov2020 and 08Nov2020. Please capture this information on the MICROBIOLOGY SPECIMEN CRF form
Nov-05-2020 10:25:30 (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-15-2020 16:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: SWABBED MATERIAL	Initial Entry
Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:25:30 (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-15-2020 16:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NASOPHARYNX	Initial Entry
Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
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Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Dec-15-2020 16:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry
Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:25:30 (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-15-2020 16:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry
Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:25:30 (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-15-2020 16:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: OTHER	Initial Entry
Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:25:30 (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
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
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Subject Initials: ---

Generated By: pfe.levisse

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Dec-15-2020 16:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NEGATIVE	Initial Entry
Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:25:30 (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-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:25:30 (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-15-2020 16:54:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NALT UNKNOWN	Initial Entry
Dec-15-2020 16:44:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:25:30 (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/04/2020 **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:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-05-2020 09:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-05-2020 09:40:35 (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
Nov-05-2020 09:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 09:40:35 (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.
Nov-05-2020 09:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES Date of Collection: Nov/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 09:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: CV02845	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

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Site Name: (1128) Ventavia Research Group

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Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Nov-09-2020 21:11:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Nov-09-2020 14:24:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Nov-06-2020 15:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW5305417;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Nov-05-2020 09:40:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: CV02845	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 **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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Nov-05-2020 10:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-05-2020 10:22:31 (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
Nov-09-2020 14:22:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Nov-09-2020 14:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-09-2020 14:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Nov-09-2020 14:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Nov-09-2020 14:21:35 (UTC-06:00) Central	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Transcription Error

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 **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:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Time (US & Canada)				
Nov-06-2020 10:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-06-2020 10:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-06-2020 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-05-2020 15:12:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Carrie Nedrick (pfe nedricke)	Query 1: Opened	DM: 'Sample Collected?' is Yes, however, no barcodes are entered. Please review and correct as appropriate.
Nov-05-2020 10:22:31 (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.
Nov-05-2020 10:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of Collection: Nov/4/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 14:22:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: SUBJECT COMPLETED HOME NASAL SWAB. SITE NASAL SW AB NOT EXPECTED	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-09-2020 14:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID:	Transcription Error
Nov-06-2020 10:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: CV02845	Initial Entry
Nov-06-2020 10:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID:	Transcription Error
Nov-06-2020 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sample ID: CV02845	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 21:11:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Nov-09-2020 14:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Nov-09-2020 14:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-09-2020 14:22:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Ent ry:	Transcription Error
Nov-06-2020 15:16:54	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Opened	DMW5305416;This Barcode is already

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 **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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-06:00) Central Time (US & Canada)				recorded more than once (for the same subject). Please review and update as appropriate.
Nov-06-2020 10:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Nov-06-2020 10:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: CV02845	Initial Entry
Nov-06-2020 10:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-06-2020 10:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Transcription Error
Nov-06-2020 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Nov-06-2020 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: CV02845	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/04/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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I.a

Date	Location	User	Value	Reason
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts:	Initial Entry
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: Not Applicable	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

090177e196ae4011\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/04/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

I.b

Date	Location	User	Value	Reason
Nov-18-2020 13:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	New Information
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: NO	Initial Entry
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: Not Applicable	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/04/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-18-2020 13:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	New Information
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

I.c

Date	Location	User	Value	Reason
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts:	Initial Entry
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable	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/04/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

			Occurrence of Visits or Contacts:	Not Applicable
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I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Not Applicable	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u>	Initial Entry
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Not Applicable	Initial Entry

I.d

Date	Location	User	Value	Reason
Nov-18-2020 13:31:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	New Information
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Type of Practitioner: Not Applicable	Initial Entry

090177e196ae4011\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/04/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

			able Occurrence of Visits or Contacts:	
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: Not Applicable	Initial Entry

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-18-2020 13:31:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	New Information
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

I.e

Date	Location	User	Value	Reason
Nov-18-2020 13:31:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable	New Information

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/04/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

			Occurrence of Visits or Contacts :	YES <i>Number of Visits or Contacts:</i> 2
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Occurrence of Visits or Contacts:	Not Applicable NO
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Occurrence of Visits or Contacts:	Not Applicable NO
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Occurrence of Visits or Contacts:	Not Applicable Not Applicable

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/04/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-18-2020 13:31:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry : YES Number of Visits or Contacts: 2	New Information
Nov-06-2020 12:49:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaard)	Query 1: Closed	Response satisfies query
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry : NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry :	Initial Entry

090177e196ae4011\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/04/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Central Time (US & Canada)				
Nov-06-2020 03:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW5294266; Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry : Not Applicable	Initial Entry

I.f

Date	Location	User	Value	Reason
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts:	Initial Entry
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: Not Applicable Occurrence of Visits or Contacts: Not Applicable	Initial Entry

090177e196ae4011\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/04/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

1.g Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-23-2020 00:03:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Nov-20-2020 09:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	Query is ambiguous

090177e196ae4011\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/04/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-20-2020 09:31:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW5437146;"Other Type of Practitioner Specify" is not null, but Occurrence of Visits or Contacts for "Other" is NO. Please review and update as appropriate.
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Nov-18-2020 13:37:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-05-2020 10:26:39 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

090177e196ae4011\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/04/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)

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

Date	Location	User	Value	Reason
Nov-06-2020 12:49:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Clos ed	Response satisfies query
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Initial Entry
Nov-06-2020 10:18:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data E ntry: NO	Initial Entry
Nov-06-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data E ntry:	Initial Entry
Nov-06-2020 03:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW5294285;Response to 'Has the subject been hospitalized due to potential COVID-19 illness?' is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-05-2020 10:26:39 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data E ntry: Not Ap plicable	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/04/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Canada)				
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090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Nov/04/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-05-2020 10:27:16 (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
Jan-13-2021 12:56:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 4: Closed	Discrepancy has been closed.
Jan-13-2021 09:39:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	updated per DM, only include the most relevant diagnosis of sepsis with acute organ dysfunction
Jan-13-2021 09:39:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Ent ry: YES <i>Respirat ory Illne ss Diag nosis:</i> sepsis Date of Diagnos is: Nov/8/ 2020	updated per DM, only include the most relevant diagnosis of sepsis with acute organ dysfunction
Jan-05-2021 07:14:22 (UTC-06:00) Central Time	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 4: Reissued: Opened	Thank you; however, please only record the most relevant

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Nov/04/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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(US & Canada)				respiratory illness diagnosis or the most severe respiratory illness diagnosis.
Dec-29-2020 17:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 4: Answered	there is no way to enter an answer to question #2 twice, kindly provide additional guidance.
Dec-24-2020 12:46:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Closed	Response satisfies query
Dec-24-2020 03:26:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 4: Opened	Multiple concepts in the term SEPSIS AND ACUTE ORGAN DYSFUNCTION. Split the term into SEPSIS and ACUTE ORGAN DYSFUNCTION and report as 2 separate entries. Thank you.
Dec-23-2020 13:29:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Closed	Discrepancy has been closed.
Dec-23-2020 11:16:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Dec-23-2020 11:16:41	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Nov/04/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)				
Dec-23-2020 11:16:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> sepsis AND a cute or gan dy sfunci on Date of Diagnos is: Nov/8/ 2020	Transcription Error
Dec-23-2020 10:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Opened	Multiple concepts in the term SEPSIS WITH ACUTE ORGAN DYSFUNCTION. Split the term into SEPSIS and ACUTE ORGAN DYSFUNCTION and report as 2 separate entries. Thank you.
Dec-23-2020 08:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Yes is selected, however, either the diagnosis details or date of diagnosis is missing. Please correct.

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Nov/04/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25

Dec-23-2020 08:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-23-2020 08:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> sepsis with a cute or organ dysfunction	Transcription Error
Dec-23-2020 01:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Reissued: Opened	Clin: Please consider updating the diagnosis as SEPSIS
Dec-22-2020 11:14:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	viral pneumonia diagnosis changed to sepsis with acute organ dysfunction
Dec-14-2020 10:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: It was stated in the SAE report #2020457282 that the subject experienced VIRAL PNEUMONIA please update the diagnosis accordingly
Nov-05-2020 10:27:16	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Nov/04/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-06:00) Central Time (US & Canada)			NO	
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3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-05-2020 10:27:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/07/2020

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: DATE OF VISIT - ILLNESS CONVALESCENT - 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-07-2020 11:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Dec/7/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-07-2020 11:38:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: COVID_A1	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/07/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Dec-07-2020 11:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-07-2020 11:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-07-2020 11:39:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-07-2020 11:38:34 (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.
Dec-07-2020 11:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: YES Date of Collection: Dec/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-07-2020 11:39:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Sample ID: BJ6SZ9	Initial Entry

5.a Sample ID

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/07/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Dec-07-2020 11:39:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: BJ6SZ9	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-07-2020 11:39:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Sample ID: BS7NGT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 11:39:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: BS7NGT	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-07-2020 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Sample ID: BHXN66	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: BHXN66	Initial Entry

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT - 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
Oct-16-2020 04:59:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-16-2020 04:59:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-16-2020 04:59:34 (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: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

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
Nov-18-2020 11:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

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

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Date	Location	User	Value	Reason
Nov-20-2020 10:32:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Deleted	Transcription Error
Nov-20-2020 10:10:50 (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: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1128) Ventavia Research Group

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Date	Location	User	Value	Reason
Dec-23-2020 12:27:07 (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: 11281153

Generated By: pfe.levisse

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-23-2020 15:45:12 (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: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

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
Nov-18-2020 11:03:22 (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
Nov-18-2020 11:03:22 (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
Mar-09-2021 10:52:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Thrombocytopenia	New Information
Mar-09-2021 10:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 3: Deleted	New Information
Mar-09-2021 10:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Hepatocellular Injury	New Information
Mar-02-2021 14:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 3: Reissued: Candidate	LAST FORM SUBMITTED HAS THE TERM ACUTE ORGAN DYSFUNCTION, AS DOES INFORM.

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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				UNSURE WHAT DM IS REQUESTING SITE TO DO.
Mar-01-2021 11:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 4: Closed	SDB updated
Mar-01-2021 06:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 3: Answered	LAST FORM SUBMITTED HAS THE TERM ACUTE ORGAN DYSFUNCTION, AS DOES INFORM. UNSURE WHAT DM IS REQUESTING SITE TO DO.
Mar-01-2021 06:07:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 4: Answered	THAT IS THE TERM ON THE LAST SUBMISSION, CORRECT
Mar-01-2021 05:39:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 4: Opened	SAE RECON: Please confirm if a follow up AE form was submitted to indicate the update in term to ACUTE MULTI ORGAN DYSFUNCTION in SDB.
Mar-01-2021 05:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 2: Closed	error - reissued
Mar-01-2021 05:37:43	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 3: Reissued:	Coding: According to SAE RECON A

090177e196ae4011\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: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

(UTC-06:00) Central Time (US & Canada)			Opened	SAE is to be submitted to have the term updated to ACUTE MULTI ORGAN DYSFUNCTION therefore please update term in INFORM Thank you
Mar-01-2021 05:37:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 2: Reissued: Opened	Coding: According to SAE RECON A SAE is to be submitted to have the term updated to ACUTE MULTI ORGAN DYSFUNCTION therefore please update term in INFORM Thank you
Feb-27-2021 14:33:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 3: Answered	PER MR ACUTE ORGAN DYSFUNCTION
Feb-27-2021 12:25:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Opened	Clarify ACUTE ORGAN DYSFUNCTION as follows...Are you reporting ACUTE SEXUAL ORGAN DYSFUNCTION or ACUTE MULTIPLE ORGAN DYSFUNCTION or other, if so edit as such. Otherwise clarify term further. Thank you
Feb-27-2021 11:45:10	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-06:00) Central Time (US & Canada)			d	
Feb-27-2021 11:45:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: ACUTE ORGAN DYSFU NCTION	Transcription Error
Feb-16-2021 01:23:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Reissued: Opened	SAE RECON: Please confirm if a follow up AE form was submitted to indicate the update in term to ACUTE MULTI ORGAN DYSFUNCTION in SDB.
Feb-15-2021 11:28:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 2: Reissued: Candidate	Pending SDB update
Feb-12-2021 16:10:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	SAE form re-faxed.
Feb-09-2021 13:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 2: Opened	SAE RECON: ACUTE ORGAN DYSFUNCTION was reported in safety database however AE in inform is "ACUTE multi-ORGAN DYSFUNCTION". Please confirm and update CRF or submit a follow-up Safety report.

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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, Not Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Jan-13-2021 12:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Jan-13-2021 09:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-13-2021 09:42:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: ACUTE multi-ORGAN DYSFUNCTION	Transcription Error
Jan-05-2021 07:15:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 1: Reissued: Opened	Thank you for confirming; however, please specify "organ dysfunction" for coding to take place. Are you reporting ACUTE SEXUAL ORGAN DYSFUNCTION or ACUTE MULTIPLE ORGAN DYSFUNCTION or other, if so edit as such. Otherwise clarify term further. Thank you
Dec-29-2020 17:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	the exact diagnosis on medical records is sepsis with acute organ dysfunction
Dec-23-2020 17:46:43	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify ACUTE ORGAN

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281153**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)				DYSFUNCTION as follows...Are you reporting ACUTE SEXUAL ORGAN DYSFUNCTION or ACUTE MULTIPLE ORGAN DYSFUNCTION or other, if so edit as such. Otherwise clarify term further. Thank you
Dec-23-2020 15:31:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: ACUTE ORGAN DYSFU NCTION	New Information
Dec-23-2020 12:46:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: VIRAL S YNDRO ME	New Information
Nov-18-2020 11:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: VIRAL P NEUMO NIA	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-25-2020 06:46:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quoter)	Query 1: Closed	Response satisfies query
Nov-23-2020 09:18:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-23-2020 09:18:56 (UTC-06:00) Central	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/4/2020 UNK:UNK	New Information

Header Text: c4591001

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Time (US & Canada)				
Nov-23-2020 03:52:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020457282 ,onset date was updated to 04Nov2020 in Safety database however, recorded as 08Nov2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Nov-18-2020 11:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/8/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-18-2020 11:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date Time: Nov/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-18-2020 11:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-19-2020 05:01:33	ACV0PFEINFP6000	auto query	Query 1: Deleted	Close Auto Query

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Site No: 1128

Subject No: 11281153

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(UTC-06:00) Central Time (US & Canada)		(autoquery)		
Nov-18-2020 11:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE VIRAL PNEUMONIA: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-18-2020 11:03:22 (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/in capacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</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.

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Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-18-2020 11:03:22 (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
Mar-09-2021 10:52:40 (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> Hepatocellular injury	New Information
Dec-23-2020 15:31:50 (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> VIRAL SYNDROME	New Information
Dec-23-2020 15:30:54 (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	Transcription Error
Dec-23-2020 15:14:59 (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>	New Information

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Header Text: c4591001

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Subject No: 11281153

Generated By: pfe.levissc

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Form Status: Data Complete, Frozen, Not Complete

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			virus exposure	
Dec-23-2020 12:48:26 (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	New Information
Nov-23-2020 01:30:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 1: Closed	Response satisfies query
Nov-20-2020 16:18:30 (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> virus	Initial Entry
Nov-20-2020 09:52:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	PI has not assessed this event, once he does, this data will be added.
Nov-19-2020 23:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "Is this event related to study treatment" is missing. Kindly review and update.

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Generated By: pfe.levisse

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Form Status: Data Complete, Frozen, Not Complete

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Subject Initials: ---

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-18-2020 11:03:22 (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
Nov-18-2020 11:03:22 (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
Nov-18-2020 11:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-18-2020 11:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-18-2020 11:03:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-19-2020 05:01:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020457282	Initial Entry

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Site No: 1128

Subject No: 11281153

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Form Status: Incomplete, Data Complete, Deleted

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

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1. Category:

Date	Location	User	Value	Reason
Nov-20-2020 10:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-20-2020 10:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-20-2020 10:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> HEADACHE	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-20-2020 10:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Nov/5/2020 16:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-20-2020 10:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NO End Date Time: Nov/11/2020 UNK:UNK	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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
Nov-20-2020 10:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-20-2020 10:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NO	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-20-2020 10:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-20-2020 10:10:50 (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
Nov-20-2020 10:10:50 (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
Nov-20-2020 10:10:50	ACV0PFEINFP6000	Thea Sonnier	<u>Data Entry:</u>	Initial Entry

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

(UTC-06:00) Central Time
(US & Canada)

(pfe.tsonnier)

RECOVERED/RESOLVED

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

Date	Location	User	Value	Reason
Nov-20-2020 10:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Dec-23-2020 12:27:07 (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-23-2020 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 10:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Hepatocellular injury	New Information
Mar-04-2021 05:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 2: Closed	Closing query to FU at a later date.
Feb-27-2021 11:47:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	information on hospital course is Not available
Feb-19-2021 09:33:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 2: Reissued: Opened	Thanks for confirming. However, no information provided regarding sepsis - BP, vasopressors, cultures - or which organs were involved. Pls submit this details in

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Header Text: c4591001

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				a FU form.
Feb-12-2021 11:41:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	Update faxed on the SAE form
Feb-07-2021 03:36:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 2: Reissued: Opened	Please provide further details on hospital course in a FU SAE form. Thanks.
Feb-02-2021 22:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	where should information be added?
Jan-27-2021 12:04:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 2: Opened	Medical_Monitor_Pls advice if information on hospital course/labs including cultures imaging is available about this SAE. Thanks
Dec-23-2020 18:54:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Dec-23-2020 16:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sepsis	updated per query
Dec-23-2020 16:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Term split into two separate entries as directed
Dec-23-2020 14:59:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term SEPSIS WITH ACUTE ORGAN DYSFUNCTION.

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

				Split the term into SEPSIS and ACUTE ORGAN DYSFUNCTION and report as 2 separate entries. Thank you.
Dec-23-2020 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sepsis with A cute Organ D ysfunction	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-23-2020 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-23-2020 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date Time: Nov/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-23-2020 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-05-2021 21:12:22	ACV0PFEINFP6000	Ricell Ann	Query 1: Deleted	Query can be

090177e196ae4011\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: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

(UTC-06:00) Central Time (US & Canada)		Piojo (pfe.quitor)		addressed internally
Dec-23-2020 16:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Sepsis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-23-2020 12:27:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-23-2020 12:27:43 (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? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Transcription Error

090177e196ae4011\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:** 11281153**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Dec-23-2020 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Dec-23-2020 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Sepsis with Acute Organ Dysfunction: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-23-2020 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Did this serious event require or prolong hospitalization? YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:27:07 (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-23-2020 12:46:02 (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> VIRAL SYNDROME	Transcription Error
Dec-23-2020 12:27:07	ACV0PFEINFP6000	Thea Sonnier	Data Entry:	Initial Entry

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

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-06:00) Central Time (US & Canada)		(pfe.tsonnier)	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-23-2020 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-23-2020 12:27:07 (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-23-2020 12:27:07 (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-23-2020 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 12:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Jan-20-2021 20:17:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020457282	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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-23-2020 15:45:12 (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-23-2020 15:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-23-2020 15:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: VIRAL SYNDROME	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-23-2020 15:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-23-2020 15:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date Time: Nov/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-23-2020 15:45:12 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 3	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)			
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-23-2020 15:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-23-2020 15:45:12 (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-29-2020 23:59:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 1: Closed	Response satisfies query
Dec-29-2020 18:13:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-29-2020 18:13:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> virus	Transcription Error
Dec-24-2020 04:26:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "If Not Related to study treatment(s),

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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

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levissc

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

				this event is due to is reported as "Other", however specify is missing? kindly review and update.
Dec-23-2020 15:45:12 (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	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-23-2020 15:45:12 (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-23-2020 15:45:12 (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-23-2020 15:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-23-2020 15:45:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-23-2020 15:45:12 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Feb-24-2021 16:08:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-24-2021 16:08:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-24-2021 16:08:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-24-2021 16:08:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-24-2021 16:08:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: INFLUENZA VACCINE	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Feb-24-2021 16:08:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Nov/12/2020	Initial Entry

090177e196ae4011\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: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-25-2021 11:09:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Jan/19/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

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-25-2021 11:09:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Participant is willing to return for V accination 3 Participant is: eligible per local/national recom mendations and confirmed to ha ve received only placebo at Vacc ination 1/2	Initial Entry

090177e196ae4011\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: 11281153

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-25-2021 11:09:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Jan/19/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-25-2021 11:09:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: ASSESS ELIGIBILITY FOR ADD ITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

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
Jan-25-2021 17:50:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/25/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-25-2021 17:50:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: OBTAINED Date Written Consent Obtained Jan/25/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

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
Jan-25-2021 17:50:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/25/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-25-2021 17:50:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-25-2021 17:50:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: COMPLETED	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/25/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-25-2021 17:51:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-25-2021 17:51:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

			Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-26-2021 08:43:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 08:43:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-26-2021 08:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 08:43:12 (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.
Jan-26-2021 08:43:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: YES Date of Collection: Jan/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-26-2021 08:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Sample ID: BHPGG3	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jan-26-2021 08:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: BHPGG3	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-26-2021 08:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Sample ID: BS87Z8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 08:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: BS87Z8	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-26-2021 08:46:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Sample ID: BS883K	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 08:46:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: BS883K	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281153**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-26-2021 08:41:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 08:41:51 (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
Jan-26-2021 08:42:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 08:41:51 (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.
Jan-26-2021 08:41:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: YES Date of Collection: Jan/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-26-2021 08:42:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Sample ID: BHPGCJ	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Jan-26-2021 08:42:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: BHPGCJ	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-25-2021 17:51:38 (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
Jan-25-2021 17:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:38 (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
Jan-25-2021 17:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/25/2021 16:02	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:38 (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
Jan-25-2021 17:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: LEFT	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

7. Route:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-25-2021 17:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-25-2021 17:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 17:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

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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I. Date of Visit

Date	Location	User	Value	Reason
Mar-09-2021 00:59:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 2: Closed	Per site confirmation_PD tracker updated
Mar-08-2021 19:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	site confirms visit 102 was conducted 7 days out of window
Mar-04-2021 00:16:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 2: Opened	PDQ: Date of visit V102_VAX4 is out of window for 7 days from V101_VAX3 Dose Date. Please verify and update. Else, confirm in query response appropriately. "[chandd38 SDQ=146082]"
Feb-28-2021 22:42:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Closed	Response satisfies query
Feb-27-2021 11:40:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	DONE
Feb-25-2021 21:10:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: Kindly review and complete 'Vaccination form' at this visit. Thank you.

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281153

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

Feb-24-2021 16:09:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry : Feb/24/202 1	Initial Entry
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090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-24-2021 16:09:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-24-2021 16:09:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-24-2021 16:09:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Feb/24/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-24-2021 16:09:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-24-2021 16:09:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-24-2021 16:09:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

			Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-24-2021 16:09:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-24-2021 16:09:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-24-2021 16:09:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-24-2021 16:21:16 (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-24-2021 16:21:16 (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 16:21:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 16:21:16 (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.
Feb-24-2021 16:21:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: YES Date of Collection: Feb/24/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-24-2021 16:21:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: Sample ID: BHPGNF	Initial Entry

5.a Sample ID

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Feb-24-2021 16:21:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: BHPGNF	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281153

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-27-2021 11:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-27-2021 11:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-27-2021 11:40:20 (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
Feb-27-2021 11:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Feb/24/2021 16:45	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-27-2021 11:40:20 (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
Feb-27-2021 11:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: LEFT	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281153

Subject Initials: ---

Generated By: pfe.levisse

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

7. Route:

Date	Location	User	Value	Reason
Feb-27-2021 11:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-27-2021 11:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-27-2021 11:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-27-2021 11:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-27-2021 11:40:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES	Initial Entry

090177e196ae4011\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281153

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-16-2020 04:59:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-19-2020 19:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-19-2020 18:59:40 (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
Oct-16-2020 04:59:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Aug-19-2020 19:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Initial Entry
Aug-19-2020 18:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Initial Entry

090177e196ae4011\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: 11281153

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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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 15:07:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe mlivingston)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/25/2020
----	--------------	--

Header Text: c4591001

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: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11281192]
2.	Birth Date:	(b) (6)/1942
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281192

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/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281192

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

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	Aug/25/2020
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: 11281192

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:	[menorrhagia]
	Start Date:	UNK/UNK/1977
	Ongoing:	NO End Date: UNK/UNK/1981
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[hysterectomy]
	Start Date:	UNK/UNK/1981
	Ongoing:	NO End Date: UNK/UNK/1981
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[osteoarthritis, bilateral knees and bilateral hips]
	Start Date:	UNK/UNK/1992
	Ongoing:	YES

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

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.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[gallstones]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1989
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[cholecystectomy]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1989
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[obesity]
	Start Date:	UNK/UNK/1977
	Ongoing:	NO End Date: UNK/UNK/2008

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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

1.g	Line/MH Number:	[7]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[gastric bypass surgery]
	Start Date:	UNK/UNK/2008
	Ongoing:	NO End Date: UNK/UNK/2008
1.h	Line/MH Number:	[8]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[acid reflux]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[prolapsed bladder]
	Start Date:	UNK/UNK/2000
	Ongoing:	NO End Date: UNK/UNK/2000

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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

1.j	Line/MH Number:	[10]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[bladder suspension surgery]
	Start Date:	UNK/UNK/2000
	Ongoing:	NO End Date: UNK/UNK/2000
1.k	Line/MH Number:	[11]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[urinary incontinence]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES
1.1	Line/MH Number:	[12]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[lasix surgery, bilateral eyes]
	Start Date:	UNK/UNK/1998
	Ongoing:	NO End Date: UNK/UNK/1998

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL 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: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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

1.m	Line/MH Number:	[13]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[cataracts, bilateral eyes]
	Start Date:	UNK/UNK/2006
	Ongoing:	NO End Date: UNK/UNK/2006
1.n	Line/MH Number:	[14]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[cataract surgery bilateral eyes]
	Start Date:	UNK/UNK/2006
	Ongoing:	NO End Date: UNK/UNK/2006
1.o	Line/MH Number:	[15]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[left ulnar nerve damage]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

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.p	Line/MH Number:	[16]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[left ulnar nerve decompression]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.q	Line/MH Number:	[17]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[implantation of bladder stimulator]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013
1.r	Line/MH Number:	[18]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[battery replacement, bladder stimulator procedure]
	Start Date:	UNK/UNK/2019
	Ongoing:	NO End Date: UNK/UNK/2019

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

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.s	Line/MH Number:	[19]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[broken pelvis]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1.t	Line/MH Number:	[20]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[broken left wrist (ulnar and radius bones)]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.u	Line/MH Number:	[21]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[broken right shoulder humerous]
	Start Date:	Feb/UNK/2020
	Ongoing:	NO End Date: Feb/UNK/2020

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/25/2020
2.	Weight:	[223.9]
3.	Unit:	LB
4.	Height:	[67.0]
5.	Unit:	in
6.	Body Mass Index:	[35.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281192**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

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 :	Aug/25/2020
2.	Randomization Number:	[240765]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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: Aug/25/2020
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	[BLG383]
5.b	Sample ID	[BLG384]
5.c	Sample ID	[BP9WSD]
5.d	Sample ID	[BP9WSF]
5.e	Sample ID	[BP9WSG]

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 11281192

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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
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	[BP9WDC]
-----	-----------	----------

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281192

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/25/2020 17:23
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

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281192

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	---

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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	Sep/16/2020
2.	Erroneous Visit	

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281192

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:	Sep/16/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281192**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Form Comments](#)[eCRF Audit Trail History](#)**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 11281192

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	NASAL_SWAB
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	[BP5KW0]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281192

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:	Sep/16/2020 15:59
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **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	Oct/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **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: Oct/14/2020
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	[BJ6SG0]
5.b	Sample ID	[BJ6SKX]
5.c	Sample ID	[BHXNG8]

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281192**Subject Initials:** ---**Generated By:** pfe.levisse**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: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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:	
----	-------------------------	--

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levissc **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: 11281192 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/14/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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:** 11281192 **Subject Initials:** ---**Generated By:** pfe.levisse **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	[]
----	-----------	-----

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: 11281192

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 Ongoing	Form Instance
1.	ADVERSE EVENT	1	Injection Site Soreness, Left arm	Jan/21/2021 17:00	NO End Date Time: Jan/22/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	worsening of right hip osteoarthritis	Feb/23/2021 UNK:UNK	YES	Repeating Pages

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Soreness, Left arm]
4.	Start Date Time:	Jan/21/2021 17:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[worsening of right hip osteoarthritis]
4.	Start Date Time:	Feb/23/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281192**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [osteoarthritis]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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	[]

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (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: 11281192

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.	1	VACCINATIONS	NO	influenza vaccination	Oct/15/2020	Repeating Pages

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[influenza vaccination]
5.	Date:	Oct/15/2020

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (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: 11281192

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (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: 11281192

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

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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: 11281192

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: 11281192

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:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281192**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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?	

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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: 11281192

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: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/7/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/7/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	---------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Death Details

1.	Date of Collection / Notification of Death:	//
----	--	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: V101_VAX3

Form: 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: 11281192

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	Jan/21/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/21/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
----	--	----------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
----	--	----------------

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/21/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form Version:** 14-Jan-2021 02:21**Site No:** 1128**Subject No:** 11281192**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST**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](#)**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V101_VAX3

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: 11281192

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: Jan/21/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BS8832]
5.b	Sample ID	[BS87YS]
5.c	Sample ID	[BHPGFL]

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 11281192

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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/21/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPPG9Y]
-----	-----------	-----------

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/21/2021 12:12
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 11281192

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	Feb/9/2021
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V102_VAX4**Form Version:** 14-Jan-2021 02:21**Site No:** 1128**Subject No:** 11281192**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST**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](#)**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001**Visit:** V102_VAX4**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:** 11281192**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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPGM8]
-----	-----------	----------

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/9/2021 12:19
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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	Mar/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: CONTACT OUTCOME

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](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/9/2021
3.	Comments:	[]

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Mar/9/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Answered Queries, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/14/2020

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: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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: 11281192

Subject Initials: ---

Generated By: pfe.levissc

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-12-2021 14:09:21 (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.

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Aug-29-2020 15:59:09 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
5	Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Not Applicable

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
5	Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-21-2021 11:29:44 (UTC-06:00) Central Time (US & Canada)	Jessica Mendoza (pfe.jmendoza)	Not Applicable

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
5	Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
6.a	Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
6.a	Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tonnier)	Not Applicable

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
5	Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
6.a	Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
6.a	Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
Comments

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Feb-09-2021 11:40:08 (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: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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-12-2021 14:09:21 (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.

Alma Sanchez	N/A	Mar-10-2021 19:29:45 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Feb-24-2021 14:06:20 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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.

Reyna Gomez	N/A	Feb-09-2021 11:36:47 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-31-2021 11:47:33 (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.

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Reyna Gomez	N/A	Jan-21-2021 16:47:26 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-21-2021 11:59:36 (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.

Jessica Mendoza	N/A	Jan-21-2021 11:28:42 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Nov-14-2020 12:29:55 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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.

April Beech	N/A	Nov-13-2020 16:18:44 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Oct-23-2020 16:31:51 (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.

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-29-2020 15:58:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-29-2020 15:58:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-29-2020 15:58:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: OBTAINED Date Written Consent Obtained Aug/25/2020	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281192

Generated By: pfe.levissc

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
Sep-02-2020 00:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Closed	Response satisfies query
Sep-01-2020 08:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-01-2020 08:38:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: 11281192	Transcription Error
Aug-31-2020 02:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 1: Opened	IVRS Reconciliation: Subject is present in inform but missing in impala. Please check and update data as appropriate. Else, clarify. Thank you.

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Aug-29-2020 15:58:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281942	Item copied from previous form
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2. Birth Date:

Date	Location	User	Value	Reason
Aug-29-2020 15:57:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1942	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-29-2020 15:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-29-2020 15:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-29-2020 15:58:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281192

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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1. Date of Visit

Date	Location	User	Value	Reason
Aug-29-2020 15:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/25/2020	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

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
Aug-29-2020 15:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/25/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-29-2020 15:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-29-2020 15:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: COMPLETED	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1.a

Date	Location	User	Value	Reason
Aug-29-2020 16:01:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical H menorrhag istory Ter ia m: Start Date UNK/UN : K/1977 Ongoing: NO End Date : UNK/U NK/198 1	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:01:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Date	Location	User	Value	Reason
Aug-29-2020 16:01:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: menorrhagia	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:01:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1977	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:01:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO End Date: UNK/UNK/1981	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-29-2020 16:01:42 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number:	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

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& Canada)

Medical History Term: hysterectomy

Start Date: UNK/UNK/1981

Ongoing: NO
End Date:

UNK/UNK/1981

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Header Text: c4591001

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Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

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1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:01:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:01:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: hysterectomy	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:01:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1981	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:01:42	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Site Name: (1128) Ventavia Research Group

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(UTC-06:00) Central Time (US & Canada)			End Date: UNK/UNK/1981	
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I.c

Date	Location	User	Value	Reason
Aug-29-2020 16:02:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 3 H Num ber: Medica osteoarthritis, I Histor bilateral knee y Term s and bilatera : 1 hips Start D UNK/UNK/1 ate: 992 Ongoin YES g:	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

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Subject Initials: ---

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1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:02:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:02:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: osteoarthritis, bilatera l knees and bilateral h ips	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:02:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1992	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:02:31	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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Central Time (US
& Canada)

1.d

Date	Location	User	Value	Reason
Aug-29-2020 16:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 4 Number: Medical History Term: gallstones Start Date UNK/UNK/1989 Ongoing: NO End Date UNK/UNK/1989	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: gallstones	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:03:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1989	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:03:15	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00)
Central Time (US
& Canada)

End Date:

UNK/UNK/1989

I.e

Date	Location	User	Value	Reason
Aug-29-2020 16:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 5 Number: Medical History Term: cholecystectomy m: Start Date UNK/UNK/1989 Ongoing: NO End Date : UNK/UNK/1989	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

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Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: cholecystectomy	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1989	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:06:49	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00)
Central Time (US
& Canada)

End Date:

UNK/UNK/1989

If

Date	Location	User	Value	Reason
Aug-29-2020 16:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 6 Number: Medical History Term: obesity Start Date UNK/UNK/1977 Ongoing: NO End Date : UNK/UNK/2008	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

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Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: obesity	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1977	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:07:28	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00)
Central Time (US
& Canada)

End Date:

UNK/UNK/2008

I.g

Date	Location	User	Value	Reason
Aug-29-2020 16:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 7 Number: Medical History Term: gastric byp ass surgery Start Date: UNK/UNK /2008 Ongoing: NO End Date: UNK/U NK/200 8	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

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Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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1.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: gastric bypass surgery	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:08:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2008	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:08:16	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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Subject Initials: ---

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(UTC-06:00) Central Time (US & Canada)			End Date: UNK/UNK/2008	
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I.h

Date	Location	User	Value	Reason
Aug-29-2020 16:08:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 8 Medical History Term: acid refl ux Start Date: UNK/U NK/2008 8 Ongoing: YES	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:08:49 (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
Aug-29-2020 16:08:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: acid reflux	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:08:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2008	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:08:49	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Central Time (US
& Canada)

Li

Date	Location	User	Value	Reason
Aug-29-2020 16:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 9 Number: Medical History Term: prolapsed bladder m: Start Date UNK/UNK : K/2000 Ongoing: NO End Date : UNK/UNK NK/2000 0	Initial Entry

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Header Text: c4591001

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1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: prolapsed bladder	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2000	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:09:41	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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(UTC-06:00)
Central Time (US
& Canada)

End Date:

UNK/UNK/2000

I,j

Date	Location	User	Value	Reason
Aug-29-2020 16:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 10 Number: Medical History bladder susp ension surge Term: ry Start Date: UNK/UNK/ 2000 Ongoing: NO End Date: UNK/U NK/2000	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: bladder suspension su rgery	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2000	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:10:37	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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Central Time (US
& Canada)

End Date:

UNK/UNK/2000

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

I.k

Date	Location	User	Value	Reason
Aug-29-2020 16:11:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 11 Number: Medical Hi urinary in story Term continenc : e Start Date: UNK/UN K/1998 Ongoing: YES	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Generated Time (GMT): 29-Mar-2021 11:25

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:11:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:11:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: urinary incontinence	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:11:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1998	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:11:14	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00)
Central Time (US
& Canada)

1.1

Date	Location	User	Value	Reason
Aug-29-2020 16:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 12 H Numb er: Medical lasix surger History y, bilateral e Term: yes Start Da UNK/UNK/ te: 1998 Ongoing NO : End Date: UNK/U NK/199 8	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

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Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:12:06 (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
Aug-29-2020 16:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: lasix surgery, bilatera l eyes	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:12:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1998	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:12:06	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)			End Date: UNK/UNK/1998	
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<i>I.m</i>				
Date	Location	User	Value	Reason
Aug-29-2020 16:13:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 13 Number: Medical cataracts, b History T ilateral eye erm: s Start Dat UNK/UNK e: /2006 Ongoing: NO End Date: UNK/U NK/200 6	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

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Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 11:25

1.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:13:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

1.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:13:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: cataracts, bilateral eyes	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:13:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2006	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:13:04	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)			End Date: UNK/UNK/2006	
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<i>I.n</i>				
Date	Location	User	Value	Reason
Aug-29-2020 16:14:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 14 H Numb er: Medical cataract surg History ery bilateral Term: eyes Start Da UNK/UNK/ te: 2006 Ongoing NO : End Date: UNK/U NK/2006	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

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Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

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1.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:14:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

1.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:14:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: cataract surgery bilat eral eyes	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:14:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2006	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:14:37	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)			End Date: UNK/UNK/2006	
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1.o

Date	Location	User	Value	Reason
Aug-29-2020 16:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 15 Number: Medical History left ulnar nerve damage Term: e Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2005	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

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Subject Initials: ---

Generated By: pfe.levisse

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1.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

1.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: left ulnar nerve dama ge	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2005	Initial Entry

1.o Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:17:55	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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(UTC-06:00) Central Time (US & Canada)			End Date: UNK/UNK/2005	
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<i>I.p</i>				
Date	Location	User	Value	Reason
Aug-29-2020 16:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 16 H Num ber: Medical left ulnar ner History ve decompre Term: ssion Start Da UNK/UNK/ te: 2005 Ongoing NO : End Date: UNK/UN K/2005	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

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Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.p Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

1.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: left ulnar nerve deco mpression	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:19:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2005	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:19:06	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)			End Date: UNK/UNK/2005	
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1.q

Date	Location	User	Value	Reason
Aug-29-2020 16:20:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 17 H Num ber: Medical implantation History of bladder sti Term: mulator Start D UNK/UNK/ ate: 2013 Ongoin NO g: End Date: UNK/UN K/2013	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.q Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:20:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

1.q Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:20:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: implantation of bladder stimulator	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:20:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2013	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:20:32	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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(UTC-06:00) Central Time (US & Canada)			End Date: UNK/UNK/2013	
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<i>I.r</i>				
Date	Location	User	Value	Reason
Aug-29-2020 16:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/ 18 MH N umber : Medic battery replace al Hist ment, bladder ory Te stimulator pro rm: cedure Start UNK/UNK/20 Date: 19 Ongoi NO ng: End Date: UNK/UNK /2019	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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1.r Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

1.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: battery replacement, bladder stimulator pr cedure	Initial Entry

1.r Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2019	Initial Entry

1.r Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:21:22	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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<i>I.s</i>				
Date	Location	User	Value	Reason
Aug-29-2020 16:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 19 Number: Medical History T broken pel vis erm: Start Date UNK/UN : K/2015 Ongoing: NO End Date : UNK/U NK/20 15	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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1.s Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

1.s Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: broken pelvis	Initial Entry

1.s Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:22:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2015	Initial Entry

1.s Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:22:20	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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(UTC-06:00) Central Time (US & Canada)			End Date: UNK/UNK/2015	
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I.t

Date	Location	User	Value	Reason
Aug-29-2020 16:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 20 H Num ber: Medica broken left wr I Histo ist (ulnar and ry Ter radius bones) m: Start D UNK/UNK/2 ate: 018 Ongoin NO g: End Date: UNK/UN K/2018	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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1.t Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

1.t Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: broken left wrist (uln ar and radius bones)	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:24:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2018	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:24:09	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

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Central Time (US
& Canada)

End Date:

UNK/UNK/2018

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Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1.u

Date	Location	User	Value	Reason
Aug-29-2020 16:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 21 H Num ber: Medical broken right History shoulder hu Term: merous Start D Feb/UNK/20 ate: 20 Ongoin NO g: End Date: Feb/UNK /2020	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.u Line/MH Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

1.u Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-29-2020 16:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: broken right shoulder humerous	Initial Entry

1.u Start Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:25:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Feb/UNK/2020	Initial Entry

1.u Ongoing:

Date	Location	User	Value	Reason
Aug-29-2020 16:25:10	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00)
Central Time (US
& Canada)

End Date:

Feb/UNK/2020

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281192

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
Aug-29-2020 16:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/25/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-29-2020 16:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 223.9	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-29-2020 16:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Aug-29-2020 16:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 67.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-29-2020 16:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-29-2020 16:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-29-2020 16:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Record Identifier: Temperature: 97.6	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Temperatur F e Unit: Temperatur FORE e Location:: HEAD	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-29-2020 16:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-29-2020 16:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 97.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-29-2020 16:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: F	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-29-2020 16:26:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: FOREHEAD	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Applicable	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sponsor-Def Not Ap ined Identifi plicabl er: e Test:: Not Ap plicabl e Result:: Not Ap plicabl e Not Done:: Not Ap plicabl e	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-29-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-29-2020 16:27:05	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Applicable	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)				
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

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
Aug-29-2020 16:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/25/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-29-2020 16:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 240765	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Aug-29-2020 16:27:57 (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-29-2020 16:27:57 (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-29-2020 16:30:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-29-2020 16:27:57 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-29-2020 16:27:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Aug/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-29-2020 16:30:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID BLG38 : 3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 16:30:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BLG383	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Aug-29-2020 16:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID BLG38 : 4	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 16:30:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BLG384	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-29-2020 16:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID BP9WS : D	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 16:30:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BP9WSD	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.d

Date	Location	User	Value	Reason
Aug-29-2020 16:30:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID BP9WS : F	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 16:30:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BP9WSF	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-29-2020 16:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID BP9WS : G	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.e Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 16:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BP9WSG	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Aug-29-2020 16:28:03 (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-29-2020 16:28:03 (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-29-2020 16:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-29-2020 16:28:03 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-29-2020 16:28:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Aug/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-29-2020 16:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID BP9WD : C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-29-2020 16:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BP9WDC	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281192

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-29-2020 16:28:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-29-2020 16:28:19 (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-29-2020 16:28:19 (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
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Aug-29-2020 16:28:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/25/2020 17:23	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-29-2020 16:28:19 (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-29-2020 16:28:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-29-2020 16:28:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-29-2020 16:28:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-29-2020 16:28:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-29-2020 16:28:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281192

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-27-2020 01:11:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nithish Maliparambil (pfe.malipn01)	Query 1: Closed	Response satisfies query
Sep-26-2020 12:29:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-26-2020 12:29:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/16/2020	Initial Entry
Sep-25-2020 09:14:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/16/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-26-2020 12:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Record Identifier:: Temperature 97.5 : Temperature F Unit: Temperature FORE Location:: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 1	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

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

2.a Temperature:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: FOREHEAD	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-26-2020 12:30:40	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)				
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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: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Sep-26-2020 12:32:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-26-2020 12:32:17 (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
Sep-26-2020 12:32:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-26-2020 12:32:17 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-26-2020 12:32:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-26-2020 12:32:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sample ID BP5KW : 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-26-2020 12:32:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: BP5KW0	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281192

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
Sep-26-2020 12:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-26-2020 12:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-26-2020 12:33:13 (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
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-26-2020 12:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/16/2020 15:59	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-26-2020 12:33:13 (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
Sep-26-2020 12:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-26-2020 12:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-26-2020 12:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-26-2020 12:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-17-2020 02:27:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Praful Prabhakar (pfe.prabhp12)	Query 1: Closed	Response satisfies query
Oct-16-2020 05:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	updated
Oct-16-2020 04:47:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Patient completed the treatment phase and reached at Visit 3. Kindly consider to update EOT form with matching V3 date or else clarify. Thank you.
Oct-14-2020 17:13:54 (UTC-06:00)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Oct/14/2020	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

Central Time (US & Canada)				
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Oct-14-2020 17:16:33 (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-14-2020 17:16:33 (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-14-2020 17:16:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 17:16:33 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128 Site Name: (1128) Ventavia Research Group

Subject No: 11281192 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 17:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-14-2020 17:16:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID BJ6SG : 0	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 17:16:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SG0	Initial Entry

5.b

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Oct-14-2020 17:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample I BJ6SK D: X	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 17:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SKX	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 17:17:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample I BHXN D: G8	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 17:17:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BHXNG8	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-16-2020 05:02:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-16-2020 05:02:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-16-2020 05:02:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: COMPLETED	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-09-2021 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Created	

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Form Created	

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

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Category:

Date	Location	User	Value	Reason
Feb-09-2021 11:39:39 (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
Feb-09-2021 11:39:39 (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
Feb-09-2021 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Injection Site Soreness, Left arm	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Feb-09-2021 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Jan/21/2021 17:00	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-09-2021 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date Time: Jan/22/2021 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-09-2021 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 1	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).

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Feb-09-2021 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-09-2021 11:39:39 (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
Feb-09-2021 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-09-2021 11:39:39 (UTC-06:00)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-09-2021 11:39:39 (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
Feb-09-2021 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-09-2021 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

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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

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Feb-09-2021 11:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Category:

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (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
Mar-12-2021 14:06:27 (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-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: worsening of right hi p osteoarthritis	Initial Entry

4. Start Date Time:

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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

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Feb/23/2021 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.lewissc

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prevent above outcomes).

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE worsening of right hip osteoarthritis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p>	Initial Entry

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Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.lewissc

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			ion? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> osteoarthritis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

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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

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.lewissc

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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: RECOVERING/RE SOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-12-2021 14:06:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Nov-13-2020 16:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-13-2020 16:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-13-2020 16:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-13-2020 16:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Nov-13-2020 16:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: influenza vaccination	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Nov-13-2020 16:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Oct/15/2020	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-21-2021 11:28:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Jan/7/2021	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levisse **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 14:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-21-2021 22:58:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-21-2021 11:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidat e	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281192 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

				complete this date.
Jan-21-2021 11:28:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-22-2021 14:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Jan/7/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-22-2021 14:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281192

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
Jan-24-2021 22:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Closed	Response satisfies query
Jan-22-2021 13:56:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Query 1: Answered	Changed data per query
Jan-22-2021 04:19:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Kindly consider to update missing LAB PREG and VACIN TRT forms or else clarify. Thank you.
Jan-21-2021 11:29:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Jan/21/2021	Initial Entry

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Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION - 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. Consent Was:

Date	Location	User	Value	Reason
Jan-21-2021 11:29:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: OBTAINED Date Written Cons ent Obtained Jan/21/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

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
Jan-21-2021 11:30:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Jan/21/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-21-2021 11:30:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-21-2021 11:30:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: COMPLETED	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sponsor-De Not A fined Identi pplica fier: ble Test:: Not A pplica ble Result:: Not A pplica ble Not Done:: Not A pplica ble	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-22-2021 13:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-22-2021 13:55:25	ACV0PFEINFP6000	Alma Sanchez	Data Entry: Not Applicable	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)		(pfe.asanchez)		
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Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Jan-21-2021 16:48:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-21-2021 16:48:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-21-2021 16:48:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 16:48:14 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-21-2021 16:48:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: YES Date of Collection : Jan/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-21-2021 16:48:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID BS883 : 2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 16:48:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BS8832	Initial Entry

5.b

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Jan-21-2021 16:48:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID BS87Y : S	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 16:48:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BS87YS	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-21-2021 16:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample I BHPGF D: L	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.c Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 16:49:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BHPGFL	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-21-2021 16:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-21-2021 16:47:26 (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
Jan-21-2021 16:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 16:47:26 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-21-2021 16:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: YES Date of Collection : Jan/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-21-2021 16:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample I BHPG9 D: Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 16:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BHPG9Y	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281192

Generated By: pfe.lewissc

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-22-2021 13:56:37 (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
Jan-22-2021 13:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-22-2021 13:56:37 (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
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Jan-22-2021 13:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/21/2021 12:12	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-22-2021 13:56:37 (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
Jan-22-2021 13:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-22-2021 13:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-22-2021 13:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-22-2021 13:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-22-2021 13:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-22-2021 13:56:37	ACV0PFEINFP6000	Alma Sanchez	Data Entry: YES	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00)
Central Time (US
& Canada)

(pfe.asanchez)

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281192

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
Feb-09-2021 11:39:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> Feb/9/2021	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sponsor-De Not A fined Identi pplica fier: ble Test:: Not A pplica ble Result:: Not A pplica ble Not Done:: Not A pplica ble	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-09-2021 11:40:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-09-2021 11:40:08	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)				
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Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Feb-09-2021 11:36:47 (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-09-2021 11:36:47 (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-09-2021 11:37:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-09-2021 11:36:47 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 11:36:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: YES Date of Collection : Feb/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-09-2021 11:37:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample I BHPGM D: 8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 11:37:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BHPGM8	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-10-2021 11:43:09 (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
Feb-10-2021 11:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-10-2021 11:43:09 (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
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090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Feb-10-2021 11:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Feb/9/2021 12:19	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-10-2021 11:43:09 (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
Feb-10-2021 11:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-10-2021 11:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-10-2021 11:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-10-2021 11:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-10-2021 11:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-10-2021 11:43:09	ACV0PFEINFP6000	Alma Sanchez	Data Entry: YES	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00)
Central Time (US
& Canada)

(pfe.asanchez)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281192

Generated By: pfe.levisse

Form: DATE OF VISIT - 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. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 11:59:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Closed	Response satisfies query
Mar-12-2021 09:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	added
Mar-12-2021 03:16:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of visit at visit

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

				103.
Mar-10-2021 19:29:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Mar/9/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Mar-10-2021 19:29:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-10-2021 19:29:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES Date of Contact: Mar/9/2021	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-12-2021 09:33:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Mar/9/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-12-2021 09:33:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREAT MENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-12-2021 09:33:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: COMPLETED	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Answered Queries, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-16-2020 05:02:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-29-2020 16:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-29-2020 15:59:00 (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
Mar-12-2021 14:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Query 1: Answered	added
Mar-12-2021	ACV0PFEINFP6000	Ricell Ann	Query 1:	SAE

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Answered Queries, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281192

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

10:24:35 (UTC-06:00) Central Time (US & Canada)		Piojo (pfe.quitor)	Opened	RECON:AER#2021264838 worsening of right hip osteoarthritis was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-16-2020 05:02:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/20 20	Initial Entry
Aug-29-2020 16:27:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2 020	Initial Entry
Aug-29-2020 15:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/25/2 020	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281192

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 13:01:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae400a\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/26/2020
----	--------------	--

Header Text: c4591001

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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11281198]
2.	Birth Date:	(b) (6)/1969
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae400e\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: 11281198

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/26/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281198

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	--	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	--	-------------------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281198

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	Aug/26/2020
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: 11281198

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[tonsillitis]
	Start Date:	UNK/UNK/1999
	Ongoing:	NO End Date: UNK/UNK/1999

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/26/2020
2.	Weight:	[153.1]
3.	Unit:	LB
4.	Height:	[69.0]
5.	Unit:	in
6.	Body Mass Index:	[22.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281198

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/26/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae400e\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: 11281198

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 :	Aug/26/2020
2.	Randomization Number:	[67721]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

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: Aug/26/2020
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	[BP9WSX]
5.b	Sample ID	[BP9WSY]
5.c	Sample ID	[BP9WSZ]
5.d	Sample ID	[BLG38F]
5.e	Sample ID	[BLG38G]

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**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:** 11281198**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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/26/2020
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	[BP9WDL]
5.b	Sample ID	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281198

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/26/2020 11:26
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

090177e196ae400e\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: 11281198

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	---

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

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	Sep/14/2020
2.	Erroneous Visit	

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/14/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281198

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/14/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 11281198

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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/14/2020
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	[BP5KSX]
-----	-----------	----------

090177e196ae400e\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: 11281198

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:	Sep/14/2020 10:31
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

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281198 **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	Oct/13/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281198 **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: Oct/13/2020
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	[BJ6SFG]
5.b	Sample ID	[BJ6SK9]
5.c	Sample ID	[BHXNB7]

090177e196ae400e\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: 11281198

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

090177e196ae400e\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: 11281198

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

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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090177e196ae400e\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: 11281198

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

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:	
----	-------------------------	--

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19**Form Version:** 20-Feb-2021 02:17**Form Status:** Not Started**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281198**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**Signs and Symptoms**

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281198**Subject Initials:** ---**Generated By:** pfe.levisse**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	[]
----	-----------	-----

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281198**Subject Initials:** ---**Generated By:** pfe.levisse**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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

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:	
----	-------------------------	--

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

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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090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

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	Aug/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
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090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/27/2020 Contact Outcome: VISIT ARRANGED
3.	Comments:	[]

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Not Done _____ //	Comments
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Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	Temperature:	Not Done _____ []	Comments
	Unit:	Not Done _____	Comments
	Temperature Location:	Not Done _____	Comments

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled
Visit on Aug/27/2020**Form:** UNPLANNED ASSESSMENT OF LOCAL
REACTION - SYSTEMIC EVENT**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281198**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[eCRF Audit Trail History](#)**Unplanned Assessment Of Local Reaction**

1.	Date of Assessment:	Aug/28/2020
2.	Injection Site Location	DELTOID MUSCLE
3.	Injection Site Body Side:	LEFT

Reaction

4.a	Reaction:	REDNESS
	Reaction Present:	NO
4.b	Reaction:	SWELLING
	Reaction Present:	NO

Symptom

5.a	Symptom:	PAIN AT INJECTION SITE
	Symptom Present:	YES
		Symptom Grade: 1 Event related to Study Treatment? YES
5.b	Symptom:	FATIGUE/TIREDNESS
	Symptom Present:	NO

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: UNPLANNED ASSESSMENT OF LOCAL
REACTION - SYSTEMIC EVENT

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.c	Symptom:	HEADACHE
	Symptom Present:	NO
5.d	Symptom:	VOMITING
	Symptom Present:	NO
5.e	Symptom:	DIARRHEA
	Symptom Present:	NO
5.f	Symptom:	NEW OR WORSENER MUSCLE PAIN
	Symptom Present:	NO
5.g	Symptom:	NEW OR WORSENER JOINT PAIN
	Symptom Present:	NO
5.h	Symptom:	CHILLS
	Symptom Present:	NO

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/13/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

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:** 11281198**Subject Initials:** ---**Generated By:** pfe.levisse**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: 11281198

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 Ongoing	Form Instance
1.	ADVERSE EVENT	1	Axillary Adenopathy, left side	Aug/26/2020 23:00	NO End Date Time: Aug/29/2020 20:00	Repeating Pages

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Axillary Adenopathy, left side]
4.	Start Date Time:	Aug/26/2020 23:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/29/2020 20:00
6.	Toxicity Grade:	1

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281198

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

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	[]

090177e196ae400e\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: 11281198

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.	1	VACCINATIONS	NO	Influenza Vaccines	Sep/29/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza Vaccine]
5.	Date:	Sep/29/2020

090177e196ae400e\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: 11281198

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

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.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae400e\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: 11281198

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

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: 11281198

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:	

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281198**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

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?	

090177e196ae400e\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: 11281198

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: 11281198

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 - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281198 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT -
Unscheduled**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281198**Subject Initials:** ---**Generated By:** pfe.levisse**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	[]
----	-----------	-----

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281198 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/21/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281198 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/21/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	---------------------------------	----

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Death Details

1.	Date of Collection / Notification of Death:	//
----	--	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/13/2020

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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

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: 11281198

Subject Initials: ---

Generated By: pfe.levissc

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	Jan-31-2021 11:48:58 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-28-2020 16:13:17 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: VITAL SIGNS - TEMP - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-29-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Temperature was collected upon entry to the clinic on 27AUG2020, but was not recorded on source. <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: VITAL SIGNS - TEMP - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
1	Aug-29-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Temperature was collected upon entry to the clinic on 27AUG2020, but was not recorded on source. <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: VITAL SIGNS - TEMP - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
2.a	Aug-29-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Temperature was collected upon entry to the clinic on 27AUG2020, but was not recorded on source. <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: VITAL SIGNS - TEMP - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
2.a	Aug-29-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Temperature was collected upon entry to the clinic on 27AUG2020, but was not recorded on source. <hr/> Not Done

Header Text: c4591001

Visit: Unplanned 1

Form: VITAL SIGNS - TEMP - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
2.a	Aug-29-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	Temperature was collected upon entry to the clinic on 27AUG2020, but was not recorded on source. <hr/> Not Done

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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Mark Koch	Approved	Jan-31-2021 11:48:58 (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.

Thea Sonnier	N/A	Jan-21-2021 17:33:40 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
-----------------	-----	--	--	---

Affidavit:

N/A

Mark Koch	Approved	Oct-23-2020 16:32:09 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae400e\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: 11281198

Subject Initials: ---

Generated By: pfe.lewissc

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.

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-28-2020 16:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-28-2020 16:11:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: STAGE 3 COHORT S	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-28-2020 16:11:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: OBTAINED Date Written Cons ent Obtained Aug/26/2020	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281198

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-28-2020 16:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281198	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-28-2020 16:11:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1969	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-28-2020 16:12:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Aug-28-2020 16:12:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
---	-----------------	-----------------------------------	--	---------------

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-28-2020 16:12:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: WHITE	Initial Entry

090177e196ae400e\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: 11281198

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-28-2020 16:13:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/26/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-28-2020 16:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/26/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-28-2020 16:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-28-2020 16:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: COMPLETED	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281198**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-28-2020 16:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Line/MH 1 Number: Medical season History T al aller erm: gies Start Dat UNK/ e: UNK/1 980 Ongoing: YES	Transcription Error
Aug-28-2020 16:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 1 Number: Medical season History T al aller erm: gies Start Dat Aug/26 e: /2020 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 16:19:26	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00)
Central Time (US
& Canada)

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-28-2020 16:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: seasonal allergies	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 16:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-28-2020 16:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: UNK/UNK/1980	Transcription Error
Aug-28-2020 16:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 26/Aug /2020. Please

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

				review and update as appropriate.
Aug-28-2020 16:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/26/2020	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 16:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-28-2020 16:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical History Term: tonsillitis Start Date UNK/UNK/1999	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Ongoing: NO End Date : UNK/U NK/199 9	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 16:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-28-2020 16:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: tonsillitis	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 16:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: UNK/UNK/1999	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 16:20:01	ACV0PFEINFP6000	Alma Sanchez	Data Entry: NO	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)		(pfe.asanchez)	End Date: UNK/UNK/1999	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281198

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
Aug-28-2020 16:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/26/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 153.1	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Aug-28-2020 16:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 69.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22.6	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-28-2020 16:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Record Id 1 entifier:: Temperatu 98.7 re:	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Temperatu F re Unit: Temperatu ORAL re Locatio CAVIT n:: Y	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 98.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: F	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/26/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Aug-28-2020 16:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-28-2020 16:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Aug-28-2020 16:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-28-2020 16:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NEGATIVE	Initial Entry

090177e196ae400e\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: 11281198

Generated By: pfe.levisse

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
Aug-28-2020 16:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/26/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-28-2020 16:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 67721	Initial Entry

090177e196ae400e\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: 11281198

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 16:22:44 (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-28-2020 16:22:44 (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-28-2020 16:27:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 16:22:44 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae400e\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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 16:22:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES Date of Collection: Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 16:27:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample I BP9WS D: X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:27:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BP9WSX	Initial Entry

5.b

090177e196ae400e\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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Aug-28-2020 16:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample I BP9WS D: Y	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:27:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BP9WSY	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 16:27:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample I BP9WS D: Z	Initial Entry

090177e196ae400e\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: 11281198

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:27:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BP9WSZ	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-28-2020 16:28:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample I BLG38 D: F	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:28:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BLG38F	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-28-2020 16:28:40	ACV0PFEINFP6000	Alma Sanchez	Data Entry: Sample I BLG38	Initial Entry

090177e196ae400e\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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)		(pfe.asanchez)	D:	G	
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:28:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BLG38G	Initial Entry

090177e196ae400e\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: 11281198

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 16:23:34 (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-28-2020 16:23:34 (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-28-2020 16:26:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Aug-28-2020 16:25:43 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however

090177e196ae400e\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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 16:25:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-28-2020 16:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Aug-28-2020 16:24:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 16:23:34 (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

090177e196ae400e\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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

				appropriate.
Aug-28-2020 16:23:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES Date of Collection: Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 16:26:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample I BP9W D: DL	Transcription Error
Aug-28-2020 16:26:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample BP9WD ID: LP	Initial Entry
Aug-28-2020 16:25:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample ID:	Transcription Error
Aug-28-2020 16:24:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample I BP9WS D: X	Initial Entry

090177e196ae400e\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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:26:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-28-2020 16:26:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BP9WDL	Transcription Error
Aug-28-2020 16:26:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Aug-28-2020 16:26:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BP9WDLP	Initial Entry
Aug-28-2020 16:25:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry:	Transcription Error
Aug-28-2020	ACV0PFEINFP6000	Alma	Data Entry:	Initial Entry

090177e196ae400e\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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

16:24:30 (UTC-06:00) Central Time (US & Canada)		Sanchez (pfe.asanchez)	BP9WSX	
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5.b

Date	Location	User	Value	Reason
Aug-28-2020 16:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample ID:	Transcription Error
Aug-28-2020 16:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample I BP9WS D: Y	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry:	Transcription Error
Aug-28-2020 16:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BP9WSY	Initial Entry

090177e196ae400e\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: 11281198

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-28-2020 16:31:04 (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-28-2020 16:31:04 (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-28-2020 16:31:04 (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
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090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Aug-28-2020 16:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/26/2020 11:26	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-28-2020 16:31:04 (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-28-2020 16:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-28-2020 16:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae400e\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: 11281198

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-28-2020 16:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N 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-28-2020 16:31:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

090177e196ae400e\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: 11281198

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
Aug-28-2020 16:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281198

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-15-2020 15:27:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/14/2020	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281198

Generated By: pfe.lewissc

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

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1. Date:

Date	Location	User	Value	Reason
Sep-15-2020 15:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/14/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-15-2020 15:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location:: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-15-2020 15:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 1	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

2.a Temperature:

Date	Location	User	Value	Reason
Sep-15-2020 15:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 97.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-15-2020 15:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-15-2020 15:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: FOREHEAD	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-15-2020 15:28:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-15-2020 15:28:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-15-2020 15:28:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/14/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

Sep-15-2020 15:28:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-15-2020 15:28:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-15-2020 15:28:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Sep-15-2020 15:28:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-15-2020 15:28:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-15-2020 15:28:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NEGATIVE	Initial Entry

090177e196ae400e\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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 10:52:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-17-2020 10:52:32 (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
Sep-17-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 10:52:32 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae400e\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: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 10:52:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES Date of Collection: Sep/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID BP5KS : X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 10:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BP5KSX	Initial Entry

090177e196ae400e\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: 11281198

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
Sep-15-2020 15:29:19 (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
Sep-15-2020 15:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-15-2020 15:29:19 (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
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090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-15-2020 15:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/14/2020 10:31	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-15-2020 15:29:19 (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
Sep-15-2020 15:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-15-2020 15:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-15-2020 15:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-15-2020 15:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281198 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 11:04:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Oct/13/2020	Initial Entry

090177e196ae400e\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: 11281198 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Oct-13-2020 11:04:57 (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-13-2020 11:04:57 (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-13-2020 11:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 11:04:57 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae400e\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: 11281198 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-13-2020 11:04:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES Date of Collection : Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-13-2020 11:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID BJ6SF : G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 11:17:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SFG	Initial Entry

5.b

090177e196ae400e\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: 11281198 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Oct-13-2020 11:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID BJ6SK : 9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 11:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SK9	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-13-2020 11:18:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample I BHXNB D: 7	Initial Entry

090177e196ae400e\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: 11281198 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

5.c Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 11:18:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BHXNB7	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-04-2020 18:56:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Closed	Response satisfies query
Oct-01-2020 12:20:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Query 1: Answer ed	See AE of Axillary Adenopathy
Sep-26-2020 19:30:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Opened	ClinQuery: : Please can you confirm the AE that lead to subject having a UNPL visit? Subject is not part of the reactogenicity subset and is not expected to have UNPL visits. Thanks
Aug-29-2020 11:24:59 (UTC-06:00)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/27/2020	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				
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090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/27/2020

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281198

Generated By: pfe.levisse

Form: UNPLANNED 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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1. Assessments

Date	Location	User	Value	Reason
Aug-29-2020 11:34:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-29-2020 11:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-29-2020 11:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> CONTACT OUTCO ME	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/27/2020

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281198

Generated By: pfe.levisse

Form: CONTACT OUTCOME - UNPLANNED - 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. Contact Type:

Date	Location	User	Value	Reason
Aug-29-2020 11:34:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Oct-01-2020 23:46:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Closed	Response satisfies query
Oct-01-2020 12:15:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Query 1: Answered	Vitals page is entered as correct. Vitals were not completed at unscheduled visit
Sep-23-2020 06:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Reissued:Opened	PDQ:RQ1: Thank you for the response, both the forms are unfrozen

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

				now, please check and update as per below query else clarify.
Sep-22-2020 15:05:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	apologies, but per site's view, Vital Signs are still frozen. Please see log line 1 in vitals.
Sep-17-2020 02:03:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Reissued:Opened	PDQ: Thank you for the response, both the forms are unfrozen now, please check and update as per below query else clarify.
Sep-16-2020 16:32:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Please unfreeze 'VITAL SIGNS' and 'UNPLANNED ASSESSMENT OF LOCAL REACTION' forms and site can update as appropriate.
Sep-01-2020	ACV0PFEINFP6000	Ashwini Patil	Query 1: Opened	DM: Contact

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

23:42:06 (UTC-06:00) Central Time (US & Canada)		(pfe.patila55)	d	Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candi date	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Aug-31-2020 00:10:14	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Opene d	DM: Contact Outcome' is

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281198

Generated By: pfe.lewissc

Form: CONTACT OUTCOME - UNPLANNED - 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

(UTC-06:00) Central Time (US & Canada)				selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Aug-29-2020 11:34:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candi date	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Aug-29-2020 11:34:39 (UTC-06:00)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Conta	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281198

Generated By: pfe.levisse

Form: CONTACT OUTCOME - UNPLANNED - 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

Central Time (US & Canada)			ct: Aug/27/2020 Contact Outcome: VISIT ARRANGED	
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090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/27/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date:

Date	Location	User	Value	Reason
Aug-29-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-29-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Record Identifier:: Not Done Temperature: Not Done Temperature Unit: Not Done Temperature Location:: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-29-2020 11:38:29 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Done	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Aug-29-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Done	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-29-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Done	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Aug-29-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Not Done	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: UNPLANNED ASSESSMENT OF LOCAL
REACTION - SYSTEMIC EVENT - eCRF Audit Trail
History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Assessment:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Aug/28/2020	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: LEFT	Initial Entry

4.a

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
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Form: UNPLANNED ASSESSMENT OF LOCAL
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Reaction:: REDN ESS Reaction P NO resent::	Initial Entry

4.a Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: REDNESS	Initial Entry

4.a Reaction Present:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28	ACV0PFEINFP6000	Linda Langdon	Data Entry: Reaction:: SWEL	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled
Visit on Aug/27/2020**Form:** UNPLANNED ASSESSMENT OF LOCAL
REACTION - SYSTEMIC EVENT - eCRF Audit Trail
History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281198**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25(UTC-06:00)
Central Time (US
& Canada)

(pfe.llangdon)

LING
**Reaction P NO
resent::****4.b Reaction:**

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: SWELLING	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Sympt PAIN AT IN om:: JECTION SI TE	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: UNPLANNED ASSESSMENT OF LOCAL
REACTION - SYSTEMIC EVENT - eCRF Audit Trail
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Symptom Present: YES Symptom Grade: 1 Event related to Study Treatment? YES	
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5.a Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Nov-03-2020 18:41:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 1: Closed	Response satisfies query
Oct-29-2020 15:43:53	ACV0PFEINFP6000	Jessica Mendoza	Query 1: Answered	AE recorded as Axillary

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Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled
Visit on Aug/27/2020**Form:** UNPLANNED ASSESSMENT OF LOCAL
REACTION - SYSTEMIC EVENT - eCRF Audit Trail
History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281198**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)		(pfe.jmendoza)		Adenopathy
Oct-26-2020 03:47:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	ClinQuery: PAIN AT INJECTION SITE: Reported on unplanned contact CRF. Please ensure this is recorded on the AE log.
Oct-25-2020 20:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 1: Candidat e	ClinQuery: PAIN AT INJECTION SITE: Reported on unplanned contact CRF. Please ensure this is recorded on the AE log.
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: YES Symptom Grade: 1 Event related to Study Treatment?	Initial Entry

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled
Visit on Aug/27/2020**Form:** UNPLANNED ASSESSMENT OF LOCAL
REACTION - SYSTEMIC EVENT - eCRF Audit Trail
History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281198**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

YES

5.b

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Symptom: FATIGUE /TIREDN ESS Symptom Present: NO	Initial Entry

5.b Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: FATIGUE/TIREDN ESS	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: UNPLANNED ASSESSMENT OF LOCAL
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Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.c

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Symptom: HEAD : ACHE Symptom NO Present::	Initial Entry

5.c Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: HEADACHE	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NO	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: UNPLANNED ASSESSMENT OF LOCAL
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History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Symptom:: VOMI TING Symptom NO Present::	Initial Entry
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5.d Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: VOMITING	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NO	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Symptom:: DIARR HEA	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: UNPLANNED ASSESSMENT OF LOCAL
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History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

& Canada)			Symptom NO Present::	
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5.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: DIARRHEA	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NO	Initial Entry

5.f

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Sympt NEW OR W om:: ORSENE MUSCLE P AIN	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: UNPLANNED ASSESSMENT OF LOCAL
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History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Sympt NO om Pr esent: :	
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5.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NEW OR WORSEN ED MUSCLE PAIN	Initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NO	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Sympt NEW OR om:: WORSENE D JOINT P AIN	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: UNPLANNED ASSESSMENT OF LOCAL
REACTION - SYSTEMIC EVENT - eCRF Audit Trail
History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Sympt NO om Pr esent::	
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5.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NEW OR WORSEN ED JOINT PAIN	Initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NO	Initial Entry

5.h

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Symptom:: CHIL LS Symptom Pr NO esent::	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled
Visit on Aug/27/2020

Form: UNPLANNED ASSESSMENT OF LOCAL
REACTION - SYSTEMIC EVENT - eCRF Audit Trail
History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.h Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: CHILLS	Initial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Sep-01-2020 15:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NO	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281198 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-14-2020 06:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Oct/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 06:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-14-2020 06:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: COMPLETED	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Form Created	

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Category:

Date	Location	User	Value	Reason
Aug-29-2020 11:55:00 (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
Aug-29-2020 11:55:00 (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
Sep-17-2020 08:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Response satisfies query
Sep-16-2020 16:35:49 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				
Sep-16-2020 16:35:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Axillary Adenophathy, left side	New Information
Sep-02-2020 09:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: Please specify which axilla is affected or whether bilateral
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Axillary Adenophathy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/26/2020 23:00	Initial Entry

5. Is the adverse event still ongoing?

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, Locked, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-20-2020 20:02:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Closed	Response satisfies query
Sep-16-2020 16:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-16-2020 16:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date Time: Aug/29/2020 20 :00	New Information
Sep-10-2020 19:21:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Opened	ClinQuery: Axillary Adenopathy: Currently marked as ongoing and duration is greater than 14 days, however this appears to be a temporary condition. Please provide an end date or clarification.

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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, Locked, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 1	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
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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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, Locked, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

& Canada)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-16-2020 16:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-16-2020 16:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RECOVERED/RE SOLVED	New Information
Sep-16-2020 16:36:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Axillary Adenopathy, left side: Response to "What was the outcome of this adverse event?" is 'Not

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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, Locked, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

				Recovered/Not Resolved' but AE End Date/Time is present.
Sep-01-2020 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-01-2020 15:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: NOT RECOVERED/NOT RESOLVED	Transcription Error
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Axillary Adenopathy: 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".
Aug-29-2020 11:55:00	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNKNOWN	Initial Entry

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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, Locked, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00)
Central Time (US
& Canada)

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Aug-29-2020 11:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON
STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Oct-19-2020 09:48:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-19-2020 09:48:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-19-2020 09:48:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-19-2020 09:48:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-19-2020 09:48:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Influenza Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-19-2020 09:48:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Sep/29/2020	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281198 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-21-2021 17:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Jan/21/2021	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281198 **Subject Initials:** ---

Generated By: pfe.levisse **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 15:02:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Participant is willin g to return for Vacc ination 3 Participant is: eligible and NO T confirmed to h ave received onl y placebo at Vac cination 1/2	Transcription Error
Jan-21-2021 17:34:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR o therwise not eligibl e	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-21-2021 17:33:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Jan/21/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-21-2021 17:33:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITION AL VACCINATION	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Subject Status

Date	Location	User	Value	Reason
Oct-14-2020 06:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-28-2020 16:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-28-2020 16:13:53 (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
Oct-14-2020 06:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/13/2020	Initial Entry
Aug-28-2020 16:22:31	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/26/2020	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281198

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)				
Aug-28-2020 16:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/26/2020	Initial Entry

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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281198

Generated By: pfe.levissc

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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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-23-2020 13:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae400e\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/31/2020
----	--------------	--

Header Text: c4591001

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: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11281241]
2.	Birth Date:	(b) (6)/1968
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281241

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/31/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281241

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	--	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	--	-------------------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281241

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	Aug/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: 11281241

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:	[hypothyroidism]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[shellfish allergy]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/31/2020
2.	Weight:	[149.5]
3.	Unit:	LB
4.	Height:	[64.5]
5.	Unit:	in
6.	Body Mass Index:	[25.3]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281241

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/31/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281241

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 :	Aug/31/2020
2.	Randomization Number:	[75978]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

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: Aug/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	[BP9WY6]
5.b	Sample ID	[BP9WY7]
5.c	Sample ID	[BP9WY8]
5.d	Sample ID	[BLG3C9]
5.e	Sample ID	[BLG3CB]

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**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:** 11281241**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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/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	[BP9WHD]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281241

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/31/2020 16:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281241

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	---

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

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	Sep/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281241

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:	Sep/21/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281241

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/21/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 11281241

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	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
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	[BP5KXM]
-----	-----------	----------

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281241

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:	Sep/21/2020 15:28
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

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281241 **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	Oct/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281241 **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: Oct/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHXNJL]
5.b	Sample ID	[BJ6SN7]
5.c	Sample ID	[BJ6STK]

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281241

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281241

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

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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090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281241

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

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:	
----	-------------------------	--

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1128

Subject No: 11281241

Generated By: pfe.levisse

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

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:	
----	-------------------------	--

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281241 **Subject Initials:** ---

Generated By: pfe.levissc **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: 11281241 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/22/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

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: 11281241 **Subject Initials:** ---

Generated By: pfe.levisse **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	[]
----	-----------	-----

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281241

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Adverse Event Report

1.	Category:	
2.	AE ID:	[]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
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).	

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

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: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (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: 11281241

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: 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: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Date:	//

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (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: 11281241

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (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: 11281241

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

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?	

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

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: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

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: 11281241

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:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281241**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

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?	

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

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: 11281241

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 - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281241 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - **Form:** ELECTRONIC SAMPLE TRACKING -
Unscheduled IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281241 **Subject Initials:** ---

Generated By: pfe.levisse **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	[]
----	-----------	-----

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281241 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Not Started

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281241 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Treatment Unblinded

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	---------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Death Details

1.	Date of Collection / Notification of Death:	//
----	--	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/22/2020

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: 11281241

Subject Initials: ---

Generated By: pfe.levissc

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: 11281241

Subject Initials: ---

Generated By: pfe.levissc

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	Oct-30-2020 15:47:37 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Sep-01-2020 10:14:58 (UTC-06:00) Central Time (US & Canada)	April Beech (pfe.abeech)	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: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Mark Koch	Approved	Oct-30-2020 15:47:37 (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.

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-01-2020 10:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Sep-01-2020 10:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-01-2020 10:14:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: OBTAINED Date Written Consent Obtained Aug/31/2020	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281241

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-01-2020 10:14:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281241	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-01-2020 10:14:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1968	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-01-2020 10:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-01-2020 10:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF S PANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-01-2020 10:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: WHITE	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281241

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 10:14:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281241

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-01-2020 10:15:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-01-2020 10:15:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-01-2020 10:15:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: COMPLETED	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281241

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Sep-01-2020 10:15:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 1 Medical His hypothy tory Term: oidism Start Date: UNK/U NK/2011 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 10:15:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-01-2020 10:15:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: hypothyroidism	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.a Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 10:15:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2011	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 10:15:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-01-2020 10:16:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical His shellfish tory Term: allergy Start Date: UNK/U NK/2011 Ongoing: YES	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 10:16:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-01-2020 10:16:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: shellfish allergy	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 10:16:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/2011	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 10:16:01	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00)
Central Time (US
& Canada)

I.c

Date	Location	User	Value	Reason
Sep-01-2020 10:16:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 3 umber: Medical His seasonal tory Term: allergies Start Date: UNK/U NK/1970 Ongoing: YES	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 10:16:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-01-2020 10:16:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: seasonal allergies	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 10:16:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: UNK/UNK/1970	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 10:16:26	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)				
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090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 149.5	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 64.5	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Record Identifier: Temperature: 97.9	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Temperatur F e Unit: Temperatur FORE e Location:: HEAD	
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: F	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/31/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-01-2020 10:17:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-01-2020 10:17:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Sep-01-2020 10:17:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281241

Generated By: pfe.levisse

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-01-2020 10:17:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-01-2020 10:17:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 75978	Transcription Error
Sep-01-2020 10:17:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 759978	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281241

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 10:19:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 10:18:03 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 10:18:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 10:19:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID BP9WY : 6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 10:19:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BP9WY6	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-01-2020 10:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID BP9WY : 7	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 10:20:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BP9WY7	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 10:20:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID BP9WY : 8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 10:20:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BP9WY8	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.d

Date	Location	User	Value	Reason
Sep-01-2020 10:24:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID BLG3C : 9	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 10:24:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BLG3C9	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-01-2020 10:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample ID BLG3C : B	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281241

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.e Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 10:24:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BLG3CB	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281241

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 10:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 10:18:09 (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
Sep-01-2020 10:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 10:18:09 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 10:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 10:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Sample I BP9WH D: D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 10:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: BP9WHD	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281241

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
Sep-01-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-01-2020 10:18:25 (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
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090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-01-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Aug/31/2020 16:32	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 10:18:25 (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
Sep-01-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-01-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-01-2020 10:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281241

Generated By: pfe.levissc

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
Sep-01-2020 10:18:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO - REACTOGENI CITY E-DIARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281241

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-22-2020 06:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/21/2020	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281241

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

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1. Date:

Date	Location	User	Value	Reason
Sep-22-2020 06:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/21/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-22-2020 06:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Record Identifier:: Temperature: 97.5 Temperature Unit: Temperature Location:: HEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-22-2020 06:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 1	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

2.a Temperature:

Date	Location	User	Value	Reason
Sep-22-2020 06:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-22-2020 06:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-22-2020 06:24:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-22-2020 06:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-22-2020 06:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-22-2020 06:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/21/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
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090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-22-2020 06:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-22-2020 06:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-22-2020 06:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined Identifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST -
eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Sep-22-2020 06:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-22-2020 06:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-22-2020 06:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NEGATIVE	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Sep-22-2020 06:25:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-22-2020 06:25:14 (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
Sep-22-2020 06:25:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 06:25:14 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 06:25:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-22-2020 06:25:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sample I BP5KX D: M	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 06:25:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: BP5KXM	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281241

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
Sep-22-2020 06:26:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-22-2020 06:26:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-22-2020 06:26:17 (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
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090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-22-2020 06:26:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/21/2020 15:28	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-22-2020 06:26:17 (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
Sep-22-2020 06:26:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-22-2020 06:26:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-22-2020 06:26:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-22-2020 06:26:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281241 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-22-2020 16:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Oct/22/2020	Transcription Error
Oct-21-2020 16:11:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Sep/21/2020	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281241 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 14:13:47 (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-22-2020 14:13:47 (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-22-2020 16:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 14:13:47 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128 Site Name: (1128) Ventavia Research Group

Subject No: 11281241 Subject Initials: ---

Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 14:13:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: YES Date of Collection: Oct/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 16:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BHXNJ D: L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 16:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BHXNJL	Initial Entry

5.b

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281241 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Oct-22-2020 16:40:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID BJ6SN : 7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 16:40:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SN7	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-22-2020 16:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID BJ6ST : K	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1128 **Site Name:** (1128) Ventavia Research Group

Subject No: 11281241 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

5.c Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 16:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6STK	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: 11281241 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 11:25

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-22-2020 14:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Oct/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-22-2020 14:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-22-2020 14:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: COMPLETED	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-22-2020 14:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-01-2020 10:17:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-01-2020 10:15:06 (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
Oct-22-2020 14:15:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/22/2020	Initial Entry
Sep-01-2020 10:17:42	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281241

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)				
Sep-01-2020 10:15:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281241

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-30-2020 15:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae4007\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levissc

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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/1/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[11281250]
2.	Birth Date:	(b) (6)/1953
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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/1/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281250

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	---	-------------------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisc

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	Sep/1/2020
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: 11281250

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:	[Post Menopausal]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

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:	Sep/1/2020
2.	Weight:	[170.3]
3.	Unit:	LB
4.	Height:	[68.5]
5.	Unit:	in
6.	Body Mass Index:	[25.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)
[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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 :	Sep/1/2020
2.	Randomization Number:	[248777]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

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: Sep/1/2020
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	[BP9WZ1]
5.b	Sample ID	[BP9WZ2]
5.c	Sample ID	[BP9WZ3]
5.d	Sample ID	[BLG3CW]
5.e	Sample ID	[BLG3CX]

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

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: Sep/1/2020
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	[BP9WHY]
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090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281250

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:	Sep/1/2020 14:09
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

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisc

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	--	---

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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/30/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281250

Generated By: pfe.lewissc

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:	Sep/30/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)
[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.lewissc

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: Sep/30/2020
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	[BP5L1T]
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090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281250

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:	Sep/30/2020 13:54
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

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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	Oct/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

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: Oct/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BJ6SVP]
5.b	Sample ID	[BJ6SPC]
5.c	Sample ID	[BHXNKR]

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levissc

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:	
----	-------------------------	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

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:	
----	-------------------------	--

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

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	[]
----	-----------	-----

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (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: 11281250

Subject Initials: ---

Generated By: pfe.levissc

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: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

eCRF Audit Trail History

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/27/2020
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: 11281250

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

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: 11281250

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	[]
----	-----------	-----

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: 11281250

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Breast Cancer	Dec/27/2020 UNK: UNK	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Breast Cancer]
4.	Start Date Time:	Dec/27/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

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: [Breast Cancer]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021026124]

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

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: 11281250

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

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	[]

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (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: 11281250

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.	1	VACCINATIONS	NO	Influenza Vaccine	Oct/23/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

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?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza Vaccine]
5.	Date:	Oct/23/2020

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (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: 11281250

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

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?	

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (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: 11281250

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

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: 11281250

Subject Initials: ---

Generated By: pfe.levissc

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: 11281250

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: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

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: 11281250

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?	

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

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: 11281250

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: 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: 11281250

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	Jan/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Jan/12/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/12/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
----	--	----------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
----	--	----------------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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 - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/12/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001**Visit:** V101_VAX3**Form Version:** 10-Dec-2020 02:23**Site No:** 1128**Subject No:** 11281250**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST**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](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

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

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BS7NFV]
5.b	Sample ID	[BS7NKS]
5.c	Sample ID	[BHPGD5]

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPFYC]
-----	-----------	----------

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281250

Generated By: pfe.lewissc

Form: VACCINATION

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

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/12/2021 12:49
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

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

eCRF Audit Trail History

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/8/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/3/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPGL7]
-----	-----------	----------

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: VACCINATION

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

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/3/2021 14:58
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281250

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

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](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/3/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281250

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281250

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

eCRF Audit Trail History

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Mar/3/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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	FOLLOW-UP
2.	Subject Status Date	Oct/27/2020

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: 11281250

Subject Initials: ---

Generated By: pfe.levissc

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: 11281250

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 17:01:36 (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.

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

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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Item	Date	User	Comment
Form	Sep-03-2020 16:06:20 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
Form	Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
1	Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
2	Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
3	Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
4	Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
5	Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
Form	Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
1	Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
2	Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
3	Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
4	Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
5	Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
6.a	Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
6.a	Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
6.a	Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-12-2021 13:26:00 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
2	Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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
5	Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
5	Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	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: 11281250

Subject Initials: ---

Generated By: pfe.levisse

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 17:01:36 (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.

Jessica Mendoza	N/A	Mar-03-2021 15:08:20 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Feb-24-2021 14:11:19 (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.

Reyna Gomez	N/A	Feb-03-2021 14:52:25 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Mark Koch	Approved	Jan-31-2021 11:53:32 (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	Jan-26-2021 14:14:59 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-21-2021 12:09:32 (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.

Roxanne Gomez	N/A	Jan-08-2021 10:24:25 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Oct-30-2020 15:48:14 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-03-2020 16:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Sep-03-2020 16:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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
Sep-03-2020 16:05:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: OBTAINED Date Written Consent Obtained Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281250

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
Sep-03-2020 16:05:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281250	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1953	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-03-2020 16:05:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: WHITE	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 16:06:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

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
Sep-03-2020 16:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sep/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-03-2020 16:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-03-2020 16:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: COMPLETED	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

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
Sep-03-2020 16:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History Term: Post Menopausal Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:07:09 (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
Sep-03-2020 16:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Post Menopausal	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: UNK/UNK/2018	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

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

Date	Location	User	Value	Reason
Sep-03-2020 16:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History Term: Hypertension Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:07:47 (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
Sep-03-2020 16:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Hypertension	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: UNK/UNK/2010	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:07:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281250

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
Sep-03-2020 16:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sep/1/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 170.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 68.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:50 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25.5	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281250

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

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Sep-03-2020 16:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Record Identifier:: 1 Temperature: 98.4 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 98.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:28:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Test: Result: Not Done:	Not Applicable Not Applicable Not Applicable Not Applicable	Initial Entry
---	-----------------	---------------------------------	--	--	---------------

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-03-2020 16:29:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

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
Sep-03-2020 16:29:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sep/1/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:29:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 248777	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: 11281250

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
Sep-03-2020 16:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 16:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 18:06:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:30:04 (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.
Sep-03-2020 16:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 18:06:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BP9WZ1	Transcription Error

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281250**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Sep-03-2020 18:06:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BP9WZ1, BP9WZ2, B P9WZ3	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 18:06:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-03-2020 18:06:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BP9WZ1	Transcription Error
Sep-03-2020 18:06:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Sep-03-2020 18:06:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BP9WZ1, BP9WZ2, BP9WZ3	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 18:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BP9WZ2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 18:06:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BP9WZ2	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 18:07:09	ACV0PFEINFP6000	Banika	Data Entry:	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: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)

Ervin (pfe.bervin)

Sample ID: BP9WZ3

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 18:07:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BP9WZ3	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-03-2020 18:07:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BLG3CW	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 18:07:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BLG3CW	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-03-2020 18:08:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BLG3CX	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 18:08:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BLG3CX	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 16:30:11 (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
Sep-03-2020 18:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:30:11 (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.
Sep-03-2020 16:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 18:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BP9WHY	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 18:05:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BP9WHY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281250

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
Sep-03-2020 16:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 16:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-03-2020 16:30:39 (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
Sep-03-2020 16:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sep/1/2020 14:09	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:30:39 (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
Sep-03-2020 16:30:39 (UTC-06:00) Central	ACV0PFEINFP6000	Banika Ervin	Data Entry: LEFT	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281250

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

Time (US & Canada)		(pfe.bervin)	
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7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 16:30:39 (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
Sep-03-2020 16:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-03-2020 16:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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
Sep-03-2020 16:30:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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
Oct-07-2020 06:12:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 2: Closed	As per site confirmation - updated PD tracker
Oct-06-2020 14:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Query 2: Answered	Subject scheduled out of window due to subject scheduling conflict.
Oct-06-2020 06:28:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nikita Singh (pfe.singhn98)	Query 2: Opened	PDQ: DOV at this visit is out of window (6 day) from DOV (01/Sep/2020) at VID1VX1L. Please either update DOV or confirm whether visit is out of window due to temporary delay of vaccination/ else provide details as appropriate.
Oct-01-2020 23:51:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Malla Reddy Chevella (pfe.chevem01)	Query 1: Closed	Response satisfies query
Oct-01-2020 10:37:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-01-2020 10:37:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/30/2020	Initial Entry
Sep-30-2020 06:28:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 1: Reissued:Opened	DM1: Thanks for response. Please respond to this query once V2 is completed.

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

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

Sep-29-2020 13:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe mlivingston)	Query 1: Answered	Visit has not yet occurred. Subject will be seen tomorrow, 30Sep2020
Sep-25-2020 10:09:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe reddy51)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 15-Sep-2020 21:54**Site No:** 1128**Subject No:** 11281250**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
Oct-01-2020 10:37:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/30/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-01-2020 10:37:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Record Identifier:: 1 Temperature: 98.0 Temperature Unit: F Temperature Locati on:: FOREHEA D	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-01-2020 10:37:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-01-2020 10:37:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-01-2020 10:37:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: F	Initial Entry

2.a Temperature Location:

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-01-2020 10:37:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sponsor-Defined Identifier: Test: Result: Not Done:	Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable	Initial Entry
---	-----------------	-------------------------	--	--	---------------

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Oct-01-2020 10:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Not Applicable	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

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-01-2020 10:41:17 (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-01-2020 10:41:17 (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
Oct-01-2020 10:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 10:41:17 (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-01-2020 10:41:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 10:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sample ID: BP5L1T	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 10:41:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: BP5L1T	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281250

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
Oct-01-2020 10:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-01-2020 10:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-01-2020 10:40:39 (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
Oct-01-2020 10:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/30/2020 13:54	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-01-2020 10:40:39 (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
Oct-01-2020 10:40:39 (UTC-06:00) Central	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: LEFT	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281250

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

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Oct-01-2020 10:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-01-2020 10:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Oct-01-2020 10:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-30-2020 01:23:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Closed	As per site confirmation - updated PD tracker
Oct-29-2020 16:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	DOV is correct, PD has been recorded and PI notified
Oct-28-2020 02:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jayesh Yeole (pfe.yeolej)	Query 1: Opened	PDQ: DOV at this visit is out of window (-1 day) from DOV (30/Sep /2020) at V2_VAX2_L. Please reconcile and update accordingly, else confirm date is correct as is.
Oct-27-2020 15:19:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Oct/27/2020	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Oct-27-2020 15:19:51 (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-27-2020 15:19:51 (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-27-2020 15:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 15:19:51 (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-27-2020 15:19:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: YES Date of Collection: Oct/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 15:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BJ6SVP	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 15:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> BJ6SVP	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-27-2020 15:35:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Sample ID: BJ6SPC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 15:35:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> BJ6SPC	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 15:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Sample ID: BHXNKR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 15:35:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> BHXNKR	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-27-2020 15:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Oct/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-27-2020 15:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-27-2020 15:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: COMPLETED	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

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
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

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
Jan-12-2021 13:34:22 (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
Jan-12-2021 13:34:22 (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
Feb-19-2021 09:39:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Closed	OK. Escalated to CRA.
Feb-12-2021 17:55:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	No Medical records received, therefore data cannot be updated. Medical records were requested 20JAN2021, site will update SAE once Medical records received.
Feb-10-2021 07:44:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Reissued:Opened	Response does not satisfy query
Feb-09-2021 14:45:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Reissued:Candidate	Response does not satisfy query
Feb-02-2021 16:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Not as of yet. I will re-send the Medical records request.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281250**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Feb-01-2021 09:38:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Reissued:Opened	Thank you for your response. Are there any updates on information requested?
Jan-26-2021 14:12:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Medical records were requested 20JAN2021, not received to date. Site will update SAE once additional information is received.
Jan-24-2021 09:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Reissued:Opened	Thanks for confirming. Please make every effort possible to obtain further information and respond to the query once additional information is available.
Jan-18-2021 16:38:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	medical records requested, update to be submitted today
Jan-18-2021 08:12:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Opened	CLINICAL_ Information on clinical course, workup (including imaging) and treatment received are not described in report submitted to safety. Kindly provide further details in a FU report. Thank you.
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Breast Cancer	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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4. Start Date Time:

Date	Location	User	Value	Reason
Jan-28-2021 09:11:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Closed	Response satisfies query
Jan-26-2021 14:14:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-26-2021 14:14:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Dec/27/2020 UNK:UNK	New Information
Jan-20-2021 04:06:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2021026124 ,onset date was recorded as 27Dec2020 in Safety database however, recorded as 07Jan2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Jan/7/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 19:15:42 (UTC-06:00) Central	ACV0PFEINFP6000	Quan Jason Gong	Query 1: Closed	Response satisfies query

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281250**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

Time (US & Canada)		(pfe.gongq)		
Jan-26-2021 14:16:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-26-2021 14:16:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 3	New Information
Jan-22-2021 09:50:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Reissued:Opened	GPDClin: Per protocol 10.3.2, G4 life-threatening meaning at risk of death at the time of the event, i.e., immediate risk of death. Most of malignancies are classified as SAE due to hospitalization or important medical events. Please clarify that with PI.
Jan-21-2021 11:23:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	This is the PI's selection
Jan-19-2021 21:17:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Opened	GPDClin: In the SAE criterion, query indicates this may not be G4 -life threatening, please consider a modification.
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	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**

Header Text: c4591001

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Site No: 1128

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Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-26-2021 19:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 3: Closed	Response satisfies query
Jan-26-2021 19:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 3: Reissued:Opened	GPDClin: Thank you for making the change. In addition, as this AE led to 3-day hospitalization per SAE report, hospitalization criterion can also be selected.
Jan-26-2021 19:16:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 4: Closed	Response satisfies query
Jan-26-2021 14:18:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Jan-26-2021 14:18:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Is this serious event associate d with congenital anomaly or birth defect? NO Did this serious event result i n death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result i n persistent or significant disa bility/incapacity?	New Information

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281250**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

			NO Is this serious event life threatening? NO Other medically important serious event YES	
Jan-26-2021 14:17:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 3: Answered	Changed data per query
Jan-19-2021 21:15:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 4: Opened	GPDClin: Per protocol 10.3.2, life-threatening is defined as the participant was at risk of death "at the time of the event", i.e., at immediate risk of death. According to the case description, please consider de-selecting the criterion.
Jan-19-2021 21:10:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 3: Opened	GPDClin: Per SAE report, the subject was hospitalized for 3 days. If it is true, please check that criterion.
Jan-17-2021 04:49:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotior)	Query 2: Closed	Response satisfies query
Jan-13-2021 16:03:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	It is now sent to Safety
Jan-13-2021 07:20:23 (UTC-06:00) Central	ACV0PFEINFP6000	Ricell Ann Piojo	Query 2: Opened	SAE RECON: Breast Cancer(Onset

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1128
Subject No: 11281250
Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Status: Data Complete
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)		(pfe.quitor)		date:07Jan2021) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Jan-13-2021 07:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Breast Cancer: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<p>Data Entry: YES Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p>	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

			Is this serious event life threatening? YES Other medically important serious event NO	
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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Breast Cancer	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-26-2021 19:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Closed	Response satisfies query
Jan-26-2021 14:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Error correction has been submitted. Subject was not hospitalized
Jan-19-2021 21:19:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Opened	GPDClin: SAE report stated the subject was hospitalized for 3 days. Please clarify if any treatment, e.g. surgery, was given. If yes, please change to "Yes".
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-01-2021 04:06:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Feb-27-2021 15:06:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	correct

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-17-2021 00:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued: Opened	SAE RECON: Per latest SAE listing outcome is still recorded as NOT RECOVERED/NOT RESOLVED. Please confirm if follow up AEM from was sent to indicate the correct outcome
Feb-15-2021 03:41:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued: Candidate	Pending SDB update
Feb-12-2021 17:52:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	updated SAE form faxed
Feb-10-2021 03:15:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2021026124,outcome was reported as NOT RECOVERED/NOT RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Jan-12-2021 13:34:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: RECOVERING/RE SOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-12-2021 13:34:22 (UTC-06:00) Central	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)				
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-17-2021 04:48:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021026124	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Oct-27-2020 15:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-27-2020 15:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-27-2020 15:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-27-2020 15:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-27-2020 15:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Influenza Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-27-2020 15:20:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Oct/23/2020	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-08-2021 10:24:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roxanne Gomez (pfe.rgomez2)	Data Entry: Jan/8/2021	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1128**Subject No:** 11281250**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[Back to Form](#)***1. Select appropriate response - Is participant willing to return for Vaccination 3?***

Date	Location	User	Value	Reason
Jan-08-2021 10:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 10:24:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-08-2021 10:24:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roxanne Gomez (pfe rgomez2)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible per local/national rec ommendations and confirme d to have received only place bo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

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
Jan-12-2021 13:25:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Jan/12/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

Form: INFORMED CONSENT - FURTHER VACCINATION - 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. Consent Was:

Date	Location	User	Value	Reason
Jan-12-2021 13:25:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: OBTAINED Date Written Consent Obtained Jan/12/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION
- eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-12-2021 13:26:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Jan/12/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-12-2021 13:26:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-12-2021 13:26:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: COMPLETED	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281250**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

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Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Test:: Result:: Not Done::	Initial Entry
			Not Applicable Not Applicable Not Applicable Not Applicable	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-12-2021 13:26:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

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1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 13:27:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 13:27:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-13-2021 17:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-13-2021 04:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-12-2021 13:27:00 (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.
Jan-12-2021 13:27:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> YES Date of Collection: Jan/12/2021	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

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5.a

Date	Location	User	Value	Reason
Jan-13-2021 17:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample ID: BS7NFV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 17:28:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BS7NFV	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-13-2021 17:29:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample ID: BS7NKS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 17:29:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BS7NKS	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-13-2021 17:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample ID: BHPGD5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 17:29:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BHPGD5	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levissc

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1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 13:27:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 13:27:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-13-2021 17:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-13-2021 04:56:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-12-2021 13:27:23 (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.
Jan-12-2021 13:27:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> YES Date of Collection: Jan/12/2021	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Jan-13-2021 17:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample ID: BHPFYC	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 17:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BHPFYC	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281250

Generated By: pfe.lewissc

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-12-2021 13:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-12-2021 13:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-12-2021 13:27:47 (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
Jan-12-2021 13:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Jan/12/2021 12:49	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-12-2021 13:27:47 (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
Jan-12-2021 13:27:47 (UTC-06:00) Central	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: LEFT	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: VACCINATION - 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

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Jan-12-2021 13:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-12-2021 13:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-12-2021 13:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-12-2021 13:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-12-2021 13:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-08-2021 10:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roxanne Gomez (pfe.rgomez2)	Data Entry: Jan/8/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-08-2021 10:24:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roxanne Gomez (pfe.rgomez2)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-03-2021 15:46:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Feb/3/2021	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sponsor-Defined Identifier: Test:: Result:: Not Done::	Initial Entry
			Not Applicable Not Applicable Not Applicable Not Applicable	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-03-2021 14:52:25 (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-03-2021 14:52:25 (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-03-2021 14:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 14:52:25 (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.
Feb-03-2021 14:52:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: YES Date of Collection: Feb/3/2021	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-03-2021 15:05:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry:	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Feb-03-2021 14:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BHPGL7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-03-2021 14:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BHPGL7	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-03-2021 15:47:52 (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
Feb-03-2021 15:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:52 (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
Feb-03-2021 15:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Feb/3/2021 14:58	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:52 (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
Feb-03-2021 15:47:52 (UTC-06:00) Central	ACV0PFEINFP6000	Alma Sanchez	Data Entry: LEFT	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281250

Generated By: pfe.levisse

Form: VACCINATION - 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

Time (US & Canada)		(pfe.asanchez)	
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7. Route:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-03-2021 15:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-03-2021 15:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-03-2021 15:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281250

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
Mar-03-2021 15:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Mar/3/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281250

Generated By: pfe.lewissc

Form: CONTACT OUTCOME - 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. Contact Type:

Date	Location	User	Value	Reason
Mar-03-2021 15:08:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-03-2021 15:08:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: YES Date of Contact: Mar/3/2021	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281250**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-05-2021 02:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_21
Mar-04-2021 01:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7592717;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-03-2021 15:11:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry : Mar/3 /2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-03-2021 15:11:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-03-2021 15:11:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281250

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-27-2020 15:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-03-2020 16:29:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 16:06:32 (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
Oct-27-2020 15:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/27/2020	Initial Entry
Sep-03-2020 16:29:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry
Sep-03-2020 16:06:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry

090177e196ae4005\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281250

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Oct-30-2020 15:27:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.lewissc

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/2/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281267

Generated By: pfe.lewissc

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[11281267]
2.	Birth Date:	(b) (6)/1973
3.	Sex:	FEMALE
4.	Ethnicity:	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: 11281267

Generated By: pfe.levissc

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/2/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281267

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	---	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	---	-------------------------

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

Generated By: pfe.lewissc

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	Sep/2/2020
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: 11281267

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)
[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SEASONAL ALLERGIES]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

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:	Sep/2/2020
2.	Weight:	[205.02]
3.	Unit:	LB
4.	Height:	[62.0]
5.	Unit:	in
6.	Body Mass Index:	[37.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)
[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

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 :	Sep/2/2020
2.	Randomization Number:	[78035]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

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: Sep/2/2020
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	[BP9X0G]
5.b	Sample ID	[BLG3H8]
5.c	Sample ID	[BLG3DS]

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

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: Sep/2/2020
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	[BP9WJM]
-----	-----------	----------

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

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:	Sep/2/2020 12:55
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

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281267

Generated By: pfe.lewissc

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	--	---

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

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/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281267

Generated By: pfe.lewissc

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:	Sep/23/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)
[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

Generated By: pfe.lewissc

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: Sep/23/2020
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	[BP5L0L]
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090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

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:	Sep/23/2020 16:56
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

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

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	Oct/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

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: Oct/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHXNJT]
5.b	Sample ID	[BJ6SNF]
5.c	Sample ID	[BJ6STS]

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

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:	
----	-------------------------	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

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:	
----	-------------------------	--

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

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	[]
----	-----------	-----

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/03/2020

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: 11281267

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	Sep/3/2020
2.	Erroneous Visit	ERRONEOUS VISIT

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/03/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)
[eCRF Audit Trail History](#)

Unplanned Assessments

	Assessments	Not Done	Comments
1.			

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/03/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)
[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	Not Applicable _____	Comments
2.	Was contact made?	Not Applicable _____	Comments
3.	Comments:	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

eCRF Audit Trail History

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/22/2020
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: 11281267

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

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: 11281267

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	[]
----	-----------	-----

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281267**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT**Form Status:** Not Started**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**Adverse Event Report**

1.	Category:	
2.	AE ID:	[]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
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).	
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.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (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: 11281267

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: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Date:	//

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (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: 11281267

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (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: 11281267

Subject Initials: ---

Generated By: pfe.levissc

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

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

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: 11281267

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

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

[Back to Form](#)

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levissc

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: 11281267

Subject Initials: ---

Generated By: pfe.lewissc

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: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

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: 11281267

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?	

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.lewissc

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: 11281267

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: 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: 11281267

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	Jan/7/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Jan/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/11/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable
----	--	----------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable
----	--	----------------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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 - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Jan/11/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

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

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPGD1]
5.b	Sample ID	[BS7NKM]
5.c	Sample ID	[BS7NFP]

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPFY7]
-----	-----------	----------

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/11/2021 16:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

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

eCRF Audit Trail History

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/7/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/3/2021
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V102_VAX4**Form Version:** 10-Dec-2020 02:23**Site No:** 1128**Subject No:** 11281267**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST**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**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/3/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPGLF]
-----	-----------	----------

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: VACCINATION

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](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/3/2021 16:29
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

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](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/3/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

eCRF Audit Trail History

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Mar/3/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

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	FOLLOW-UP
2.	Subject Status Date	Oct/22/2020

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: 11281267

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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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: 11281267

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-10-2021 15:00:33 (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.

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

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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Item	Date	User	Comment
Form	Sep-02-2020 17:24:24 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, 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	Oct-26-2020 11:41:40 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	
Form	Sep-02-2020 17:26:12 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
Form	Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
1	Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
2	Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
3	Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
4	Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
5	Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
Form	Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
1	Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
2	Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
3	Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
4	Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
5	Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
6.a	Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/03/2020

Form: UNPLANNED VISIT - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Nov-16-2020 14:34:57 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: UNPLANNED 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	Nov-16-2020 14:34:57 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/03/2020

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Nov-13-2020 13:23:31 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
Form	Nov-13-2020 13:23:09 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
Form	Nov-13-2020 09:20:19 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	subject is not on reactogenicity subset.
Form	Nov-11-2020 18:04:09 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject is not on reactogenicity subset. _____ Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: CONTACT OUTCOME - UNPLANNED - 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	Nov-13-2020 13:23:31 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
1	Nov-13-2020 13:23:09 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
1	Nov-13-2020 09:20:19 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	subject is not on reactogenicity subset.
1	Nov-11-2020 18:04:09 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject is not on reactogenicity subset. <hr/> Not Applicable

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: CONTACT OUTCOME - UNPLANNED - 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	Nov-13-2020 13:23:31 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
2	Nov-13-2020 13:23:09 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
2	Nov-13-2020 09:20:19 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	subject is not on reactogenicity subset.
2	Nov-11-2020 18:04:09 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject is not on reactogenicity subset. <hr/> Not Applicable

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: CONTACT OUTCOME - UNPLANNED - 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	Nov-13-2020 13:23:31 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable
3	Nov-13-2020 13:23:09 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
3	Nov-13-2020 09:20:19 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	subject is not on reactogenicity subset.
3	Nov-11-2020 18:04:09 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject is not on reactogenicity subset. <hr/> Not Applicable

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-13-2021 11:15:32 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

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Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

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Item	Date	User	Comment
3	Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

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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	Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
5	Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

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Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

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Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

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Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
2	Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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
3	Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
4	Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
5	Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Feb-03-2021 15:53:56 (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: 11281267

Subject Initials: ---

Generated By: pfe.levisse

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-10-2021 15:00:33 (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.

Reyna Gomez	N/A	Mar-10-2021 10:12:15 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Mar-08-2021 17:01:59 (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.

Jessica Mendoza	N/A	Mar-03-2021 11:28:30 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Mark Koch	Approved	Feb-24-2021 14:12:43 (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-03-2021 15:53:45 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-21-2021 12:06:42 (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.

Roxanne Gomez	N/A	Jan-08-2021 10:49:06 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Nov-16-2020 14:44:21 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

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	Nov-16-2020 14:33:01 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Nov-14-2020 12:31:19 (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	Nov-11-2020 18:03:00 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Oct-30-2020 15:50:18 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

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.

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-02-2020 17:21:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Sep-02-2020 17:23:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

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
Sep-02-2020 17:21:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: OBTAINED Date Written Consent Obtained Sep/2/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281267

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
Sep-02-2020 17:20:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281267	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-02-2020 17:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1973	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-02-2020 17:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-02-2020 17:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-02-2020 17:21:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: WHITE	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-02-2020 17:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/2/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

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
Sep-02-2020 17:24:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/2/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-02-2020 17:24:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-02-2020 17:24:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: COMPLETED	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

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1.a

Date	Location	User	Value	Reason
Oct-26-2020 11:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 1 ber: Medical Histor SEASONAL AL y Term: LERGIES Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-26-2020 11:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-26-2020 11:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: SEASONAL ALLERGIES	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Oct-26-2020 11:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: UNK/UNK/2005	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Oct-26-2020 11:42:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281267

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
Sep-02-2020 17:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> Sep/2/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> 205.02	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> 62.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:31 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 37.5	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281267

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

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Sep-02-2020 17:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location:: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: FOREHEAD	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sponsor-Defined Id Not Applic entifier: able Test:: Not Applic able Result:: Not Applic able Not Done:: Not Applic able	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-02-2020 17:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

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
Sep-02-2020 17:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/2/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-02-2020 17:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 78035	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Sep-02-2020 17:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-02-2020 17:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-27-2020 02:29:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nithish Maliparambil (pfe.malipn01)	Query 2: Closed	Response satisfies query
Sep-26-2020 11:13:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	entered
Sep-22-2020 21:25:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 2: Opened	DM: Serum barcode BLG3DS has been received by the lab for Visit 1. Please review and update or submit SCF.
Sep-03-2020 08:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-02-2020 23:17:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Opened	DM: 'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281267**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25

				review and correct as appropriate.
Sep-02-2020 17:30:33 (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.
Sep-02-2020 17:30:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Date of Collection: Sep/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 08:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sample ID: BP9X0G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 08:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: BP9X0G	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 08:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sample ID: BLG3H8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 08:30:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: BLG3H8	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: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.c

Date	Location	User	Value	Reason
Sep-26-2020 11:13:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sample ID: BLG3DS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-26-2020 11:13:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: BLG3DS	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Sep-02-2020 17:30:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-02-2020 17:30:47 (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
Sep-03-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-02-2020 23:17:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Opened	DM: 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-02-2020 17:30:47 (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.
Sep-02-2020 17:30:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Date of Collection: Sep/2/2020	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: 11281267

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

5.a

Date	Location	User	Value	Reason
Sep-03-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sample ID: BP9WJM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: BP9WJM	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

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
Sep-02-2020 17:31:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-02-2020 17:31:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-02-2020 17:31:54 (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
Oct-01-2020 03:05:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Closed	As per site confirmation - updated PD tracker
Sep-30-2020 06:44:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	unplanned visit completed
Sep-28-2020 02:10:36 (UTC-06:00) Central Time	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Reissued: Opened	PDQ RQ1: Thank you for the response. As per section 8.43 of

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

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

(US & Canada)				CRF Completion Requirements, please consider updating UNPLANNED VISIT form and select appropriate Contact Outcome option present on UNPLANNED VISIT (UNPL) form
Sep-26-2020 11:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	subject was contacted by phone, confirmed she had left knee swelling, that comes and goes since 2013. Has also been added to medical history.
Sep-07-2020 02:22:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	PDQ: Subject has reported with Severe symptoms/reactions on '2020-09-05'. Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate. "[malipn01 SDQ=4056]"
Sep-02-2020 17:31:54 (UTC-06:00)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/2/	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

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

Central Time (US & Canada)			2020 1 2:55	
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5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-02-2020 17:31:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-02-2020 17:31:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-02-2020 17:31:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-02-2020 17:31:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-02-2020 17:31:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281267

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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I. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-22-2020 04:39:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe.margap03)	Query 2: Closed	As per site confirmation
Sep-28-2020 07:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Premraj Bhoyar (pfe.bhoyap)	Query 2: Reissued: Candidate	Email sent for CRA/Signant notification on 28Sep2020.
Sep-26-2020 11:27:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	subject was inadvertently entered into reactogenicity subset in error, on the trialmax system. EDC and source are correct.
Sep-25-2020 07:54:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Premraj Bhoyar (pfe.bhoyap)	Query 2: Opened	eDiary: Per Trial Max, Subject is the subset of 'Reactogenicity Diary collection'. Please review and consider to update response for 'Reactogenicity diary collection' as 'Yes', else clarify in query response. Thanks
Sep-25-2020 07:54:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Premraj Bhoyar (pfe.bhoyap)	Query 1: Closed	vax 1 eDiary data available.
Sep-04-2020 07:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	S Vijaya Kumar (pfe.kumas557)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'No' however VAX 1 eDiary records are available for the

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281267

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

				subject. Please verify and update. Else, confirm in query response appropriately.
Sep-02-2020 17:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO - REACTOGENICITY E -DIARY NOT 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: 11281267

Generated By: pfe.levissc

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-27-2020 02:29:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nithish Maliparambil (pfe.malipn01)	Query 1: Closed	Response satisfies query
Sep-26-2020 11:28:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-26-2020 11:28:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/23/2020	Initial Entry
Sep-26-2020 04:34:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-26-2020 11:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Record Identifier:: 1 Temperature: 97.6 Temperature Unit: F Temperature Locati on:: FOREHE AD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 97.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-26-2020 11:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-26-2020 11:28:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

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
Sep-26-2020 11:29:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-26-2020 11:29:11 (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
Sep-27-2020 15:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-26-2020 23:47:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pankaj Bhoir (pfe.bhoirp02)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-26-2020 11:29:11 (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.
Sep-26-2020 11:29:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Date of Collection: Sep/23/2020	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Sep-27-2020 15:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sample ID: BP5L0L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-27-2020 15:16:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: BP5L0L	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

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
Sep-26-2020 11:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-26-2020 11:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-26-2020 11:30:04 (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
Sep-26-2020 11:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/23/2020 16:56	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-26-2020 11:30:04 (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
Sep-26-2020 11:30:04 (UTC-06:00) Central	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: LEFT	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

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

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Sep-26-2020 11:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-26-2020 11:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-26-2020 11:30:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-22-2020 18:05:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Oct/22/2020	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281267**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-22-2020 18:05:19 (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-22-2020 18:05:19 (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-22-2020 18:11:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 18:05:19 (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-22-2020 18:05:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: YES Date of Collection: Oct/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 18:11:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BHXNJT	Initial Entry

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: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 18:11:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BHXNJT	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-22-2020 18:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BJ6SNF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 18:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SNF	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-22-2020 18:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BJ6STS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 18:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6STS	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/03/2020

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: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-17-2020 02:42:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 2: Deleted	As per DM query
Nov-16-2020 14:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Nov-16-2020 14:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-13-2020 22:32:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jayesh Yeole (pfe.yeolej)	Query 1: Opened	DM: This visit is marked as Erroneous; however, data is present on UNPL form. Please confirm if visit occurred or entered in error. If in error, please clear the data entered on UNPL and update the form accordingly or else clarify. Thank you.
Nov-13-2020 13:22:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/03/2020

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: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

				visit.
Sep-30-2020 06:47:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sep/3/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Nov-16-2020 14:34:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: ERRONEOUS VISIT	Initial Entry
Nov-16-2020 14:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	New Information
Nov-13-2020 13:22:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: ERRONEOUS VISIT	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/03/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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I. Assessments

Date	Location	User	Value	Reason
Nov-16-2020 19:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 2: Closed	Response satisfies query
Nov-16-2020 14:34:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-16-2020 14:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Nov-16-2020 14:33:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	New Information
Nov-14-2020 04:14:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 2: Reissued:Opened	This UNPL form within the visit which were started in error should be marked Not Applicable at form comment level. Please update.
Nov-13-2020 13:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	Changed data per query
Nov-13-2020 13:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 2: Reissued:Opened	all forms unfrozen, please update
Nov-13-2020 09:21:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	please unfreeze so that site may tick the erroneous visit button
Nov-13-2020 04:23:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 2: Reissued:Opened	Please confirm if visit occurred. If no, please Tick the

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001 Visit: Unplanned 1 - Unscheduled Visit on Sep/03/2020 Form Version: 22-Apr-2020 21:04 Site No: 1128 Subject No: 11281267 Generated By: pfe.levissc					Form: UNPLANNED 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				
					Erroneous Visit button on the DOV CRF. Any forms within the visit which were started in error should be marked Not Applicable at form comment level.				
Nov-12-2020 15:26:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered		this was entered per DM request, per the comment the subject is not in the reactogenicity subset, however was inadvertently enrolled in trialmax, and a DCF was submitted to get it corrected. DM still wanted the data entered here, therefore site complied.				
Nov-11-2020 20:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Opened		'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.				
Nov-11-2020 18:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate		'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.				
Sep-30-2020 06:50:10 (UTC-06:00) Central	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted		Close Auto Query				

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/03/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)				
Sep-30-2020 06:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Sep-30-2020 06:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: CONTACT OUTCOME	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/03/2020

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: CONTACT OUTCOME - UNPLANNED - 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. Contact Type:

Date	Location	User	Value	Reason
Nov-13-2020 13:23:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-13-2020 13:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Nov-13-2020 09:20:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Nov-11-2020 18:04:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-11-2020 18:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Sep-30-2020 06:50:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Nov-13-2020 13:23:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-13-2020 13:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-13-2020 09:20:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-11-2020 18:04:09 (UTC-06:00) Central	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/03/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)				
Nov-11-2020 18:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Sep-30-2020 06:50:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO <i>If No, why?</i> called subject 3 times and received no call back.	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Nov-13-2020 13:23:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Nov-13-2020 13:23:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Nov-13-2020 09:20:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Initial Entry
Nov-13-2020 05:12:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 1: Closed	Response satisfies query
Nov-11-2020 18:04:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Nov-11-2020 18:03:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-11-2020 18:03:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Nov-11-2020 01:01:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan	Query 1: Opened	ClinQuery:Subject not in the reactogenicity subset

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Sep/03/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1128**Subject No:** 11281267**Generated By:** pfe.levissc**Form:** CONTACT OUTCOME - UNPLANNED - 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

		(pfe.srujas)		so unplanned contact CRF unwarranted. Please ensure that any adverse events reported during the contact are added to the AE log or SOD form under potential C-19 illness visit as appropriate. Thank you.
Nov-10-2020 15:40:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 1: Candidate	ClinQuery:Subject not in the reactogenicity subset so unplanned contact CRF unwarranted. Please ensure that any adverse events reported during the contact are added to the AE log or SOD form under potential C-19 illness visit as appropriate. Thank you.
Sep-30-2020 06:50:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: It was confirmed at visit 2 23SEP2020 subject had left knee swelling, that comes and goes since 2013. Has also been added to medical history source.	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: 11281267

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-22-2020 18:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Oct/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-22-2020 18:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-22-2020 18:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: COMPLETED	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-08-2021 10:49:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roxanne Gomez (pfe.rgomez2)	Data Entry: Jan/7/2021	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1128**Subject No:** 11281267**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[Back to Form](#)***1. Select appropriate response - Is participant willing to return for Vaccination 3?***

Date	Location	User	Value	Reason
Jan-08-2021 10:49:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 10:49:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-08-2021 10:49:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roxanne Gomez (pfe rgomez2)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

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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I. Date of Visit

Date	Location	User	Value	Reason
Jan-13-2021 11:15:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/11/2021	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

Form: INFORMED CONSENT - FURTHER VACCINATION - 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. Consent Was:

Date	Location	User	Value	Reason
Jan-13-2021 11:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: OBTAINED Date Written Consent Obtained Jan/11/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION
- eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

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
Jan-13-2021 11:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/11/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-13-2021 11:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-13-2021 11:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: COMPLETED	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sponsor-Defined Identifier: Test:: Result:: Not Done::	Initial Entry Not Applicable Not Applicable Not Applicable Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-13-2021 11:16:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Jan-13-2021 11:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-13-2021 11:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-13-2021 11:20:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-13-2021 11:20:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-13-2021 11:20:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES Date of Collection: Jan/11/2021	New Information
Jan-13-2021 11:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Jan-13-2021 11:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281267**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

				collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Jan-13-2021 11:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-13-2021 11:19:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample ID: BHPGD1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 11:19:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BHPGD1	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-13-2021 11:20:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample ID: BS7NKM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 11:20:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BS7NKM	Initial Entry

5.c

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Mar-10-2021 10:12:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BS7NFP	Initial Entry
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5.c Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 10:12:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BS7NFP	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Jan-13-2021 11:21:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-13-2021 11:21:18 (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
Jan-13-2021 11:22:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 11:21:18 (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.
Jan-13-2021 11:21:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES Date of Collection: Jan/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-13-2021 11:22:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample ID: BHPFY7	Initial Entry

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Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Jan-13-2021 11:22:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> BHPFY7	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-13-2021 11:17:56 (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
Jan-13-2021 11:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-13-2021 11:17:30 (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
Jan-13-2021 11:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/11/2021 16:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-13-2021 11:17:30 (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
Jan-13-2021 11:17:30 (UTC-06:00) Central	ACV0PFEINFP6000	Alma Sanchez	Data Entry: LEFT	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: VACCINATION - 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

Time (US & Canada)		(pfe.asanchez)	
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7. Route:

Date	Location	User	Value	Reason
Jan-13-2021 11:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-13-2021 11:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-13-2021 11:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-13-2021 11:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-13-2021 11:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

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-08-2021 10:49:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roxanne Gomez (pfe.rgomez2)	Data Entry: Jan/7/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-08-2021 10:49:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roxanne Gomez (pfe.rgomez2)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

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
Feb-03-2021 15:53:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Feb/3/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-12-2021 09:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Monica McGuire (pfe.mcguim15)	Query 1: Closed	Thank you for your response. Request for MedHx CRF unlock submitted. Please ensure postmenopausal status is entered.
Mar-11-2021 17:28:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	subject is post menopausal since unk/unk/2018
Mar-10-2021 01:14:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	CLINQUERY- Please clarify why pregnancy tests were not performed for this subject. Subject is <60 yrs old and has no MH of surgical sterilization. Test is required for WOCBP. Please review and record

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281267**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

				PDs, if applicable.
Mar-08-2021 12:03:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Monica McGuire (pfe.mcguim15)	Query 1: Candidate	CLINQUERY- Please clarify why pregnancy tests were not performed for this subject. Subject is <60 yrs old and has no MH of surgical sterilization. Test is required for WOCBP. Please review and record PDs, if applicable.
Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Sponsor-Defined Id Not Applic entifier: able Test:: Not Applic able	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Result::	Not Applicable
			Not Done::	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 15:53:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-03-2021 16:00:51 (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-03-2021 16:00:51 (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-03-2021 16:01:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 16:00:51 (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.
Feb-03-2021 16:00:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: YES Date of Collection: Feb/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-03-2021 16:01:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BHPGLF	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Feb-03-2021 16:01:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BHPGLF	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-03-2021 17:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-03-2021 17:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-03-2021 17:21:35 (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
Feb-03-2021 17:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Feb/3/2021 16:29	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-03-2021 17:21:35 (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
Feb-03-2021 17:21:35 (UTC-06:00) Central	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: LEFT	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: VACCINATION - 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

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Feb-03-2021 17:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-03-2021 17:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-03-2021 17:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-03-2021 17:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-03-2021 17:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281267

Generated By: pfe.levissc

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
Mar-03-2021 11:28:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Mar/3/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281267

Generated By: pfe.levisse

Form: CONTACT OUTCOME - 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. Contact Type:

Date	Location	User	Value	Reason
Mar-03-2021 11:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-03-2021 11:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: YES Date of Contact: Mar/3/2021	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281267**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-05-2021 02:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_21
Mar-04-2021 01:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7592715;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-03-2021 15:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry : Mar/3 /2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-03-2021 15:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-03-2021 15:13:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281267

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-22-2020 18:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-02-2020 17:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-02-2020 17:24:49 (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
Oct-22-2020 18:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/22/2020	Initial Entry
Sep-02-2020 17:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/2/2020	Initial Entry
Sep-02-2020 17:24:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/2/2020	Initial Entry

090177e196ae4006\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281267

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Oct-30-2020 15:34:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281296

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	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/8/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: DEMOGRAPHY

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

Demography

1.	Subject ID	[11281296]
2.	Birth Date:	(b) (6)/1945
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

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/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281296

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	---	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	---	-------------------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

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	Sep/8/2020
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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

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

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetic Neuropathy]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes Mellitus II]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroesophageal Reflux Disease]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Restless Leg Syndrome]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery Disease]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	UNK/UNK/1974
	Ongoing:	NO End Date: UNK/UNK/1974
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Polycystic Ovaries]
	Start Date:	UNK/UNK/1974
	Ongoing:	NO End Date: UNK/UNK/1974
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[right rotator cuff tear]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

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:	Sep/8/2020
2.	Weight:	[172.5]
3.	Unit:	LB
4.	Height:	[60.5]
5.	Unit:	in
6.	Body Mass Index:	[33.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.3]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)
[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae400b\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: 11281296

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 :	Sep/8/2020
2.	Randomization Number:	[254174]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

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: Sep/8/2020
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	[BLG3J6]
5.b	Sample ID	[BLG3FP]
5.c	Sample ID	[BHXNBR]

090177e196ae400b\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: 11281296

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: Sep/8/2020
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	[BP9WLJ]
-----	-----------	----------

090177e196ae400b\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: 11281296

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:	Sep/8/2020 12:54
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

090177e196ae400b\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: 11281296

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

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/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281296

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:	Sep/29/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)
[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

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: Sep/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5L1J]
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090177e196ae400b\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: 11281296

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:	Sep/29/2020 16:45
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

090177e196ae400b\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: 11281296

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	Oct/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

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: Oct/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHXNKJ]
5.b	Sample ID	[BJ6SP5]
5.c	Sample ID	[BJ6SVH]

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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	Dec/23/2020
2.	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
Dec/23/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Dec/23/2020
2.	Date of First Symptom Started:	Dec/23/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/25/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	YES

Symptoms - Other

5.a	Symptoms - Other Text:	[soreness of back of head]
-----	------------------------	----------------------------

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.b	Symptoms - Other Text:	[nausea]
5.e	Symptoms - Other Text:	[severe right shoulder pain]

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: 11281296

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 Dec/23/2020 **Form:** MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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	SITE	Comments
2.	Sample Type	NASAL_SWAB_SELF	Comments
3.	Sample Collected?	NO	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[subject was hospitalized for motor vehicle accident, swab was not done.]	Comments

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

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: 11281296

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	SITE	Comments
2.	Sample Type	NASAL_SWAB	Comments
3.	Sample Collected?	NO	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[subject was hospitalized for motor vehicle accident, swab was not done.]	Comments

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**eCRF Audit Trail History****Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	YES
		Has the subject been in intensive care due to potential COVID-19 illness?
		NO

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1. DELETED	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages
2.	HOSPITALIZATION STATUS	HOSPITAL	Dec/23/2020	NO Discharge Date: Dec/25/2020	Repeating Pages

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

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[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Hospitalization Details

1.	Hospitalization Category:	Not Applicable _____	Comments
2.	Hospitalization Term:	Not Applicable _____	Comments
3.	Admission Date:	Not Applicable _____ //	Comments
4.	Ongoing?	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Dec/23/2020
4.	Ongoing?	NO Discharge Date: Dec/25/2020

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: 11281296

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.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Respiratory Treatment

1.	What is the treatment Identifier?	Not Done _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Done _____	Comments
3.	Treatment:	Not Done _____	Comments
4.	Treatment:	Not Done _____ []	Comments
5.	Start Date:	Not Done _____ //	Comments
6.	Ongoing?	Not Done _____	Comments

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [motor vehicle accident] Date of Diagnosis: Dec/23/2020
3.	Toxicity Grade:	3

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: 11281296

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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[Form Audit Trail](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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.	Not Done	Not Done	Not Done	Not Done	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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[eCRF Audit Trail History](#)

Lab Chemistry Details

1.	Lab Panel:	Not Done _____	Comments
2.	Laboratory Name and Address	Not Done _____ []	Comments
3.	Collection Date:	Not Done _____ //	Comments
4.	Specimen Type:	Not Done _____	Comments

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.b	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		
5.c	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.d	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done _____	Comments
		[]	
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____	Comments
		Low [] High [] Unit	
5.e	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Bilirubin_PX21	
	Result:	Not Done _____	Comments
		[]	
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____	Comments
		Low [] High [] Unit	

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5 f	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

5.g	Sponsor ID:	Not Done _____	Comments
		[]	
	Test:	Creatinine_PX48	
	Result:	Not Done _____	Comments
		[]	
Not Done:	Not Done _____	Comments	
LNMT	Not Done _____	Comments	
	Low [] High [] Unit		

090177e196ae400b\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: 21-Aug-2020 02:51

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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.	HEMATOLOGY	unknown	Dec/23/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					1	Hemoglobin_PX1	9.5	
					2	Hematocrit_PX2	[]	
					3	Erythrocytes_PX3	[]	
					5	Platelets_PX5	[]	
					7	Leukocytes_PX7	[]	
					608	Neutrophils_PX608	[]	
					609	Eosinophils_PX609	[]	
					612	Monocytes_PX612	[]	
					610	Basophils_PX610	[]	
					611	Lymphocytes_PX611	[]	

090177e196ae400b\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: 20-Feb-2021 02:18

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Category for Lab Test	Vendor Name (DEFINITION)	Collection Date:	Specimen Type	Lab Result			Form Instance
2.	HEMATOLOGY	UNKNOWN	Dec/24/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					1	Hemoglobin_PX1	9.1	
					2	Hematocrit_PX2	[]	
					3	Erythrocytes_PX3	[]	
					5	Platelets_PX5	[]	
					7	Leukocytes_PX7	[]	
					608	Neutrophils_PX608	[]	
					609	Eosinophils_PX609	[]	
					612	Monocytes_PX612	[]	
					610	Basophils_PX610	[]	
					611	Lymphocytes_PX611	[]	
3.	HEMATOLOGY	UNKNOWN	Dec/25/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					1	Hemoglobin_PX1	9.1	
					2	Hematocrit_PX2	[]	
					3	Erythrocytes_PX3	[]	
					5	Platelets_PX5	[]	
					7	Leukocytes_PX7	[]	
					608	Neutrophils_PX608	[]	
					609	Eosinophils_PX609	[]	
					612	Monocytes_PX612	[]	

090177e196ae400b\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: 20-Feb-2021 02:18

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
					610	Basophils_PX610	[]	
					611	Lymphocytes_PX611	[]	

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[unknown]
3.	Collection Date:	Dec/23/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[9.5]
	Not Done:	
	LNMT	Low [unknown] High [unknown] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology**Form Version:** 20-Feb-2021 02:18**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[UNKNOWN]
3.	Collection Date:	Dec/24/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[9.1]
	Not Done:	
	LNMT	Low [UNKNOWN] High [UNKNOWN] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology**Form Version:** 20-Feb-2021 02:18**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[UNKNOWN]
3.	Collection Date:	Dec/25/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[9.1]
	Not Done:	
	LNMT	Low [UNKNOWN] High [UNKNOWN] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Date:	Vital Signs Details			Form Instance					
1.	Dec/23/2020	<table border="1"><thead><tr><th>Record Identifier:</th><th>Systolic:</th><th>Diastolic:</th></tr></thead><tbody><tr><td>1</td><td>193</td><td>90</td></tr></tbody></table>	Record Identifier:	Systolic:	Diastolic:	1	193	90		Repeating Pages
Record Identifier:	Systolic:	Diastolic:								
1	193	90								

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Vital Signs

1.	Date:	Dec/23/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[193]
	Diastolic:	[90]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[65]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Date:	Vital Signs Details		Form Instance
1.	Dec/23/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	96.0	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Vital Signs

1.	Date:	Dec/23/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[96.0]

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: 11281296

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.	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Done _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done _____ []	Comments

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: 11281296

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.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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?	Not Done _____ []	Comments
2.	Category:	Not Done _____	Comments
3.	Concomitant Medications Pre-specified:	Not Done _____	Comments
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).	Not Done _____ []	Comments
5.	Start Date:	Not Done _____ //	Comments
6.	Ongoing?	Not Done _____	Comments

090177e196ae400b\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: 11281296

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.	Dec/23/2020	OTHER <i>If other, specify:</i> PELVIS	X-RAY	NORMAL	Repeating Pages
2.	Dec/23/2020	HEAD	CT SCAN	NORMAL	Repeating Pages
3.	Dec/23/2020	OTHER <i>If other, specify:</i> SPINE	CT SCAN	NORMAL	Repeating Pages
4.	Dec/23/2020	CHEST	X-RAY	NORMAL	Repeating Pages
5.	Dec/23/2020	OTHER <i>If other, specify:</i> LEFT WRIST	X-RAY	NORMAL	Repeating Pages
6.	Dec/23/2020	OTHER <i>If other, specify:</i> RIGHT SHOULDER	X-RAY	NORMAL	Repeating Pages

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Imaging

1.	Date of Assessment:	Dec/23/2020
2.	Location of Assessment:	OTHER If other, specify: [PELVIS]
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Imaging

1.	Date of Assessment:	Dec/23/2020
2.	Location of Assessment:	HEAD
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Imaging

1.	Date of Assessment:	Dec/23/2020
2.	Location of Assessment:	OTHER If other, specify: [SPINE]
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

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Imaging

1.	Date of Assessment:	Dec/23/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Imaging

1.	Date of Assessment:	Dec/23/2020
2.	Location of Assessment:	OTHER If other, specify: [LEFT WRIST]
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Imaging

1.	Date of Assessment:	Dec/23/2020
2.	Location of Assessment:	OTHER If other, specify: [RIGHT SHOULDER]
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Feb/22/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date of Visit

1.	Date of Visit	Feb/22/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
on Feb/22/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/22/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPGK9]
5.b	Sample ID	[BS8815]
5.c	Sample ID	[BS8876]

090177e196ae400b\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: 11281296

Subject Initials: ---

Generated By: pfe.levissc

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: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

eCRF Audit Trail History

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/27/2020
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: 11281296

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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: 11281296

Subject Initials: ---

Generated By: pfe.levisse

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	[]
----	-----------	-----

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: 11281296

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 Ongoing	Form Instance
1.	ADVERSE EVENT	1	MOTOR VEHICLE ACCIDENT	Dec/23/2020 UNK:UNK	NO End Date Time: Dec/25/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	severe right shoulder pain	Dec/23/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	post traumatic pain	Dec/23/2020 UNK:UNK	NO End Date Time: Jan/2/2021 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	soreness to back of head	Dec/23/2020 UNK:UNK	NO End Date Time: Dec/25/2020 UNK:UNK	Repeating Pages
5. DELETED	ADVERSE EVENT	5	nausea	Dec/23/2020 UNK:UNK	NO End Date Time: Dec/25/2020 UNK:UNK	Repeating Pages
6. DELETED	ADVERSE EVENT	6	vomiting	Dec/23/2020 UNK:UNK	NO End Date Time: Dec/25/2020 UNK:UNK	Repeating Pages
7.	ADVERSE EVENT	7	anemia	Dec/23/2020 UNK:UNK	YES	Repeating Pages

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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)	[MOTOR VEHICLE ACCIDENT]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/25/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [AUTOMOBILE ACCIDENT]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021005966]

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)[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)	[severe right shoulder pain]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [automotive accident]
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?:	NOT RECOVERED/NOT RESOLVED

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[post traumatic pain]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/2/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
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: [automotive accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021005966]

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[soreness to back of head]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/25/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [automotive accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Deleted**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1.	Category:	ADVERSE EVENT
2.	AE ID:	[§]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[nausea]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/25/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [automotive accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

***** THIS REPEATING FORM HAS BEEN DELETED *****

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Deleted**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[vomiting]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/25/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [automotive accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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***** THIS REPEATING FORM HAS BEEN DELETED *****

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[anemia]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [IRON DEFFICIENCY]
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?:	NOT RECOVERED/NOT RESOLVED

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

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	[]

090177e196ae400b\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: 11281296

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.	1	VACCINATIONS	NO	Influenza Vaccination	Oct/22/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza Vaccination]
5.	Date:	Oct/22/2020

090177e196ae400b\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: 11281296

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

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?	

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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: 11281296

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levissc

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: 11281296

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	Form: LAB URINALYSIS - PREGNANCY TEST
Visit: Unplanned Vaccination - Unscheduled	Form Status: Not Started
Form Version: 20-Feb-2021 02:14	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281296	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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?	

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001	Form: CONTACT OUTCOME - MONTH 1
Visit: Unplanned Vaccination - Unscheduled	Form Status: Not Started
Form Version: 10-Oct-2020 15:57	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281296	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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: 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: 11281296

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	Dec/30/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001	Form: DATE OF VISIT
Visit: V101_VAX3	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281296	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levissc	

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/4/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

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](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/4/2021
----	--------------	---

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	---	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	---	-------------------------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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 - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/4/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

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

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/4/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHXN7H]
5.b	Sample ID	[BS7NJ3]
5.c	Sample ID	[BS7ND5]

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/4/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPFX0]
-----	-----------	----------

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: VACCINATION

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

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/4/2021 13:07
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001	Form: TREATMENT UNBLINDED
Visit: Disposition - Unscheduled	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:03	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281296	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Dec/30/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001	Form: DATE OF VISIT
Visit: V102_VAX4	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281296	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/25/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	Not Applicable _____	Comments
2.	Lab Sub-Panel:	Not Applicable _____	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable _____ []	Comments
5.	Specimen Type:	Not Applicable _____	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHPGB8]
-----	-----------	----------

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: VACCINATION

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

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/25/2021 10:14
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/22/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: CONTACT OUTCOME

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

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/22/2021
3.	Comments:	[]

Header Text: c4591001	
Visit: V104_MONTH6	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: 11281296	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	Form: CONTACT OUTCOME
Visit: V104_MONTH6	Form Status: Not Started
Form Version: 22-Apr-2020 21:04	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281296	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Feb/22/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

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	FOLLOW-UP
2.	Subject Status Date	Oct/27/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281296

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: 11281296

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 17:03:12 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

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](#)

Item	Date	User	Comment
Form	Sep-08-2020 13:47:36 (UTC-06:00) Central Time (US & Canada)	Jerred Downs (pfe.jdowns)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
Form	Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	Jerred Downs (pfe.jdowns)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
1	Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	Jerred Downs (pfe.jdowns)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
2	Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	Jerred Downs (pfe.jdowns)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
3	Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	Jerred Downs (pfe.jdowns)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
4	Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	Jerred Downs (pfe.jdowns)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Item	Date	User	Comment
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Header Text: c4591001

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Item	Date	User	Comment
6.a	Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	Jerred Downs (pfe.jdowns)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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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Item	Date	User	Comment
Form	Sep-29-2020 17:19:29 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

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Subject No: 11281296

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Item	Date	User	Comment
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Header Text: c4591001

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

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Item	Date	User	Comment
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Item	Date	User	Comment
4	Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

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Form Version: 06-Jul-2020 21:54

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Item	Date	User	Comment
5	Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
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Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6	Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
7	Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
8	Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
9	Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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	Feb-02-2021 21:31:17 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	.
Form	Feb-01-2021 14:23:03 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject was hospitalized for motor vehicle accident, swab was not done. <hr/> 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

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Item	Date	User	Comment
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Item	Date	User	Comment
Form	Feb-02-2021 21:30:38 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	.
Form	Feb-01-2021 14:23:28 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject was hospitalized for motor vehicle accident, swab was not done. <hr/> Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on
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Form: HOSPITALIZATION DETAILS - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Item	Date	User	Comment
Form	Feb-02-2021 10:28:47 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: HOSPITALIZATION DETAILS - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Item	Date	User	Comment
4	Feb-02-2021 10:28:47 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1128

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Subject No: 11281296

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Item	Date	User	Comment
1	Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

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Item	Date	User	Comment
2	Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

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Item	Date	User	Comment
3	Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

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5	Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

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Item	Date	User	Comment
6	Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
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Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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Generated By: pfe.levisse

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Item	Date	User	Comment
Form	Feb-02-2021 10:33:13 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: ILLNESS DETAILS - SEVERE - Comments

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Item	Date	User	Comment
1	Feb-02-2021 10:33:13 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable

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Item	Date	User	Comment
2	Feb-02-2021 10:33:13 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Applicable
2	Feb-01-2021 14:34:18 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	subject did not have any of these events Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
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Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Status: Data Complete, 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
Form	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

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Item	Date	User	Comment
5.a	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

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Site Name: (1128) Ventavia Research Group

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Item	Date	User	Comment
5.b	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Item	Date	User	Comment
5.b	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

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Item	Date	User	Comment
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Item	Date	User	Comment
5.c	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

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Item	Date	User	Comment
5.d	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

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Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Status: Data Complete, 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
5 f	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Status: Data Complete, 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
5 f	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Status: Data Complete, 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
5.g	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Status: Data Complete, 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
5.g	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
5.g	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Status: Data Complete, 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
5.g	Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-28-2021 12:13:53 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Feb-28-2021 12:13:53 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Feb-28-2021 12:13:53 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Feb-28-2021 12:13:53 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
5	Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6	Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	Jen Vasilio (pfe.jvasilio)	Not Done

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION -
Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-06-2021 17:08:02 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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	Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
5	Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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
6.a	Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	Alma Sanchez (pfe.asanchez)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

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Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
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Header Text: c4591001

Visit: V102_VAX4

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Site Name: (1128) Ventavia Research Group

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Item	Date	User	Comment
4	Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

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Generated Time (GMT): 29-Mar-2021 11:25

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Visit: V102_VAX4

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Item	Date	User	Comment
6.a	Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

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Item	Date	User	Comment
6.a	Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6.a	Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

090177e196ae400b\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: 11281296

Subject Initials: ---

Generated By: pfe.levisse

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 17:03:12 (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 15:27:07 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Feb-24-2021 14:14:57 (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	Feb-01-2021 13:08:40 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-31-2021 11:55:50 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae400b\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: 11281296

Subject Initials: ---

Generated By: pfe.levisse

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.

Erin McLeod	N/A	Jan-25-2021 09:47:49 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-21-2021 12:09:59 (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	Dec-31-2020 15:13:42 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Oct-31-2020 12:24:33 (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.

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281296

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
Sep-08-2020 13:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Sep-08-2020 13:46:42 (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: 11281296

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
Sep-08-2020 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-08-2020 13:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: OBTAINED Date Written Consent Obtained Sep/8/2020	Transcription Error
Sep-08-2020 13:47:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Sep-08-2020 13:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: OBTAINED Date Written Consent Obtained Aug/8/2020	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281296

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
Sep-08-2020 13:46:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281296	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1945	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-08-2020 13:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-08-2020 13:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-08-2020 13:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: WHITE	Initial Entry

090177e196ae400b\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: 11281296

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-08-2020 13:47:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/8/2020	Initial Entry

090177e196ae400b\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: 11281296

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
Sep-08-2020 13:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-08-2020 13:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-08-2020 13:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: COMPLETED	Initial Entry

090177e196ae400b\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: 11281296
Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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.a

Date	Location	User	Value	Reason
Oct-01-2020 07:35:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Line/MH Number: 1 Medical History Term: Diabetic Neuropathy Start Date: UNK/UNK/2005 Ongoing: YES	updated to diabetic neuropathy, per phone verification with the subject.
Sep-08-2020 13:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Neuropathy Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 13:48:27 (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
Oct-06-2020 21:25:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 1: Closed	Response satisfies query
Oct-01-2020 07:35:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated to diabetic neuropathy, per phone verification with the subject.
Oct-01-2020 07:35:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Diabetic Neuropathy	updated to diabetic neuropathy, per phone verification with the subject.
Sep-10-2020 19:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 1: Opened	ClinQuery: Neuropathy: Please add the underlying cause (e.g. diabetes, hypertension etc.) to

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

				the reported term; if no underlying cause has been identified please add "idiopathic".
Sep-08-2020 13:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Neuropathy	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2005	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 13:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-08-2020 13:48:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Diabetes Mellitus II Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 13:48:39 (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
Sep-08-2020 13:48:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Diabetes Mellitus II	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:48:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1995	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 13:48:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-08-2020 13:48:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 3 ber: Medical Histor Gastroesophageal Ref y Term: lux Disease Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 13:48:55 (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
Sep-08-2020 13:48:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Gastroesophageal Reflux Disease	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:48:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2005	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 13:48:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-08-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Hypertension Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:05 (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
Sep-08-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Hypertension	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2005	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-08-2020 13:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Insomnia Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:19 (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
Sep-08-2020 13:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Insomnia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2005	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-08-2020 13:49:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Restless Leg Syndrome Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:32 (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
Sep-08-2020 13:49:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Restless Leg Syndrome	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2005	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-08-2020 13:49:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History T Coronary Artery Di erm: sease Start Date: UNK/UNK/2009 Ongoing: YES	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:44 (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
Sep-08-2020 13:49:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Coronary Artery Disease	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2009	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 13:49:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-08-2020 13:50:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Hyperlipidemia Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 13:50:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-08-2020 13:50:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Hyperlipidemia	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:50:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2005	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 13:50:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Sep-08-2020 13:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Hysterectomy Start Date: UNK/UNK/1974 Ongoing: NO End Date: UNK/UNK/1974	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

L.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 13:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

L.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-08-2020 13:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Hysterectomy	Initial Entry

L.i Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1974	Initial Entry

L.i Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 13:50:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO End Date: UNK/UNK/1974	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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](#)

<i>Lj</i>				
Date	Location	User	Value	Reason
Sep-08-2020 13:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: Polysystic Ovaries Start Date: UNK/UNK/1974 Ongoing: NO End Date: UNK/UNK/1974	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

Lj Line/MH Number:

Date	Location	User	Value	Reason
Sep-08-2020 13:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 10	Initial Entry

Lj Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Jan-18-2021 09:24:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 2: Closed	Response satisfies query
Jan-15-2021 09:55:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Query 2: Answered	updated
Jan-15-2021 08:43:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 2: Reissued: Opened	SAE report submitted to safety (AER#2021005966) - SAE reported Motor vehicle accident.
Jan-15-2021 08:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	kindly confirm what "report" DM is referencing, so site can confirm.
Jan-12-2021 13:37:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 2: Opened	Per report the subject has a " had a history of a right rotator cuff tear.", however this additional information is missing on CRF. Please revise and update accordingly.
Sep-09-2020 08:41:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Sep-08-2020 17:05:58	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle	Query 1: Opened	Clarify POLYSYSTIC

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

(UTC-06:00) Central Time (US & Canada)		(pfe.PFETMS)		OVARIES as follows...Should the spelling be POLYCYSTIC OVARIES? If so, edit. Otherwise clarify. Thank you.
Sep-08-2020 13:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Polysystic Ovaries	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1974	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-08-2020 13:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO End Date: UNK/UNK/1974	Initial Entry

1.k

Date	Location	User	Value	Reason
Jan-15-2021 09:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Te right rotator cuff t rm: ear Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

1.k Line/MH Number:

Date	Location	User	Value	Reason
Jan-15-2021 09:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Jan-15-2021 09:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: right rotator cuff tear	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Jan-15-2021 09:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: UNK/UNK/2015	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Jan-15-2021 09:55:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1128**Subject No:** 11281296**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[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-08-2020 13:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/8/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 172.5	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 60.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 33.1	Initial Entry

7.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1128

Subject No: 11281296

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

Sep-08-2020 13:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Record Identifier:: 1 Temperature: 97.3 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:21 (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
Sep-08-2020 13:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 97.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: FOREHEAD	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:**

Date	Location	User	Value	Reason
Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

			Not Done::	Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

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
Sep-08-2020 13:52:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/8/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-08-2020 13:52:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 254174	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:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-09-2020 09:19:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-09-2020 09:19:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-09-2020 09:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 09:19:32 (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.
Sep-09-2020 09:19:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES Date of Collection: Sep/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-09-2020 09:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BLG3J6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 09:19:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BLG3J6	Initial Entry

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
 Form Version: 22-Apr-2020 21:03
 Site No: 1128
 Subject No: 11281296
 Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.b

Date	Location	User	Value	Reason
Sep-09-2020 09:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BLG3FP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 09:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BLG3FP	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-09-2020 09:24:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BHXNBR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 09:24:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BHXNBR	Initial Entry

090177e196ae400b\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:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-09-2020 09:23:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-09-2020 09:23:55 (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
Sep-09-2020 09:24:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 09:23:55 (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.
Sep-09-2020 09:23:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES Date of Collection: Sep/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-09-2020 09:24:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BP9WLJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 09:24:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BP9WLJ	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1128**Subject No:** 11281296**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[Back to Form](#)**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-08-2020 13:53:18 (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
Sep-08-2020 13:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-08-2020 13:53:18 (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
Sep-08-2020 13:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sep/8/2020 12:54	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-08-2020 13:53:18 (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
Sep-08-2020 13:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281296

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

Sep-08-2020 13:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-08-2020 13:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSER VATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-08-2020 13:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281296

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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I. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-08-2020 13:53:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO - REACTOGENICITY E-DIARY NOT 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: 11281296

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-29-2020 17:18:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sep/29/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

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

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I. Date:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sep/29/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 17:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: FOREHEAD	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:**

Date	Location	User	Value	Reason
Sep-29-2020 17:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-29-2020 17:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-29-2020 17:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

			Not Done::	Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 17:19:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae400b\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:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-29-2020 17:19:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-29-2020 17:19:50 (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
Sep-29-2020 17:25:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 17:19:50 (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.
Sep-29-2020 17:19:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Date of Collection: Sep/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 17:25:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BP5L1J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 17:25:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BP5L1J	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281296

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
Sep-29-2020 17:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-29-2020 17:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-29-2020 17:20:29 (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
Sep-29-2020 17:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sep/29/2020 16:45	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-29-2020 17:20:29 (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
Sep-29-2020 17:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae400b\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: 11281296

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

Sep-29-2020 17:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-29-2020 17:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSER VATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-29-2020 17:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

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
Oct-27-2020 10:55:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> Oct/27/2020	Initial Entry

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:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-27-2020 10:55:50 (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-27-2020 10:55:50 (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-27-2020 13:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 10:55:50 (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-27-2020 10:55:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES Date of Collection: Oct/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 13:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BHXNKJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 13:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BHXNKJ	Initial Entry

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: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.b

Date	Location	User	Value	Reason
Oct-27-2020 13:10:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BJ6SP5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 13:10:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SP5	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 13:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BJ6SVH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 13:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BJ6SVH	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 03:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 4: Closed	Closed as Convalescent Visit completed.
Feb-22-2021 16:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 4: Answered	CONVA visit completed
Feb-22-2021 04:32:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 4: Reissued:Opened	PDQ: RQ2: Thank you for response, per response CONVA visit scheduled 17-Feb- 2021.However CONVA still missing. Please provide scheduled CONVA visit or else clarify.
Feb-15-2021 00:30:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 4: Reissued:Candidate	PDQ: RQ2: Per your response; Please respond to query once data available. Thank you.
Feb-12-2021 09:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 4: Answered	subject scheduled on 17FEB2021 for Convalescent visit
Feb-10-2021 02:14:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 4: Reissued:Opened	PDQ RQ2: Per response, please confirm scheduled date and update data once available as appropriate. Thank you.
Feb-09-2021 11:36:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 4: Answered	convalescent visit is required per sponsor, no matter how out of date it is, site will call subject to schedule a convalescent visit.
Feb-09-2021 04:39:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 4: Reissued:Opened	PDQ: RQ1: Per site response, Please review CONVA visit once entered. Thank

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

				you.
Feb-04-2021 20:21:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 4: Answered	convalescent visit not done or scheduled, as site did not complete a COVID illness visit. Site was told to enter MVA symptoms as a COVID illness visit on 01FEB2021. Kindly confirm if site should complete a late convalescent visit.
Feb-04-2021 04:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 4: Opened	PDQ: Convalescent visit is missing and 35+ days (43) have passed since COVID Illness Visit. If visit occurred record the data as a matching CONVA visit; if the visit did not occur attempt to schedule the visit and obtain the CONVA sample else clarify.
Feb-03-2021 04:20:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 3: Deleted	Query is invalid or does not apply
Feb-02-2021 21:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: 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-02-2021 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe.riddlj)	Query 1: Closed	Response satisfies query
Feb-02-2021 09:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	per DM, the MVA symptoms are to be reported as a COVID illness visit, with no swabs
Feb-02-2021 00:30:20 (UTC-06:00) Central Time	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	Date of Visit is completed but Date of

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

(US & Canada)				Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-01-2021 14:19:33 (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.
Feb-01-2021 14:19:33 (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.
Feb-01-2021 14:19:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-01-2021 14:19:33 (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 Dec/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 15:28:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Closed	Response satisfies query
Feb-07-2021 13:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-07-2021 13:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO Date of Last Symptom Resolved: Dec/25/2020	New Information
Feb-05-2021 10:58:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Reissued:Opened	Clin: Please query remain open until resolution
Feb-02-2021 21:07:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	site to clarify stop dates with subject and update as appropriate
Feb-02-2021 14:13:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Opened	Clin: Please confirm that at least one symptom is ongoing
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES	Initial Entry

4.a

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom NEW OR INCREASED S s: HORTNESS OF BREATH Symptom NO Present:	Initial Entry
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4.c Symptoms:

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-02-2021 10:26:50 (UTC-06:00) Central Time	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: NEW OR INCREASED	Transcription Error

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(US & Canada)			MUSCLE PAIN Symptom P NO resent:	
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P YES resent:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-03-2021 08:44:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Feb-02-2021 10:26:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Transcription Error
Feb-02-2021 09:58:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	per DM, the MVA symptoms are to be reported as a COVID illness visit, with no swabs
Feb-02-2021 09:51:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clin: Does this refer to post traumatic pain recorded as AE due to MVA? If so, it should not also be recorded as symptom of potential COVID illness.
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
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090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry
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4.f Symptoms:

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry
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4.h Symptoms:

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms: VOMITING Symptom Present: YES	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-01-2021 14:20:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-02-2021 10:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms - Other: soreness of back of head	Transcription Error (DELETED)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Feb-01-2021 14:20:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms - Other: soreness of back of head	Initial Entry
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5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-03-2021 08:44:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Feb-02-2021 10:27:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: soreness of back of head	Transcription Error (DELETED)
Feb-02-2021 09:58:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	per DM, the MVA symptoms are to be reported as a COVID illness visit, with no swabs
Feb-02-2021 09:41:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clin: As soreness of back of head is recorded as AE due to MVA, it should not also be recorded as symptom of potential COVID illness.
Feb-01-2021 14:20:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: soreness of back of head	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-01-2021 14:21:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms - Other: nausea	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-01-2021 14:21:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: nausea	Initial Entry

5.c

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Feb-02-2021 10:27:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms - Other: severe right shoulder pain	Transcription Error (DELETED)
Feb-01-2021 14:21:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptoms - Other: severe right shoulder pain	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-03-2021 08:44:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Feb-02-2021 10:27:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: severe right shoulder pain	Transcription Error (DELETED)
Feb-02-2021 09:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	per DM, the MVA symptoms are to be reported as a COVID illness visit, with no swabs
Feb-02-2021 09:41:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clin: As severe right shoulder pain is recorded as AE due to MVA, it should not also be recorded as symptom of potential COVID illness.
Feb-01-2021 14:21:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: severe right shoulder pain	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
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8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Feb-01-2021 14:21:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**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:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-02-2021 21:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Feb-02-2021 21:31:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Feb-01-2021 14:23:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-02-2021 21:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry
Feb-02-2021 21:31:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Feb-01-2021 14:23:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-03-2021 02:54:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_05
Feb-02-2021 21:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-02-2021 21:31:30 (UTC-06:00)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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

Central Time (US & Canada)				
Feb-02-2021 21:31:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Feb-02-2021 13:46:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe.riddlj)	Query 1: Reissued:Opened	DM: Please update 'Sample Collected' to No and provide the reason not collected (such as Illness Visit not performed) in Item 2 per CRF Completion Requirements 8.16. First clear the Not Applicable comment then update CRF.
Feb-02-2021 09:59:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	per DM, the MVA symptoms are to be reported as a COVID illness visit, with no swabs
Feb-02-2021 02:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7088964;Sample Collected is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Feb-01-2021 14:23:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	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
Feb-02-2021 21:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: subject was hospitalized for motor vehicle accident, swab was not done.	Initial Entry
Feb-02-2021 21:31:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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

Feb-01-2021 14:23:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
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090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**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:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-02-2021 21:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Feb-02-2021 21:30:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Feb-01-2021 14:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-02-2021 21:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry
Feb-02-2021 21:30:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Feb-01-2021 14:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-03-2021 02:54:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_05
Feb-02-2021 21:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-02-2021 21:30:59 (UTC-06:00)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**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:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Central Time (US & Canada)				
Feb-02-2021 21:30:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry
Feb-02-2021 13:46:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe.riddlj)	Query 1: Reis sued:Opened	DM: Please update 'Sample Collected' to No and provide the reason not collected (such as Illness Visit not performed) in Item 2 per CRF Completion Requirements 8.16. First clear the Not Applicable comment then update CRF.
Feb-02-2021 09:59:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Ans wered	per DM, the MVA symptoms are to be reported as a COVID illness visit, with no swabs
Feb-02-2021 02:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW7088965;Sample Collected is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Feb-01-2021 14:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicabl e	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-02-2021 21:30:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: subject was hospitalized for motor vehic le accident, swab was not done.	Initial Entry
Feb-02-2021 21:30:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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

Feb-01-2021 14:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Feb-27-2021 15:28:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Transcription Error
Feb-24-2021 07:23:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Transcription Error
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: EMERGENCY ROOM	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	
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I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-27-2021 15:28:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Transcription Error
Feb-24-2021 07:23:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Transcription Error
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.c

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Feb-27-2021 15:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Cont acts: NO	Transcription Error
Feb-24-2021 07:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Transcription Error
Feb-24-2021 07:25:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or Cont acts: NO	Transcription Error
Feb-24-2021 07:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Transcription Error
Feb-01-2021 14:24:51 (UTC-06:00) Central Time	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(US & Canada)			Type of Practitioner:	OTHE R	
			Occurrence of Visits or Cont acts:	NO	

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

If Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: OTHER	Initial Entry

If Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-27-2021 15:27:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Transcription Error
Feb-24-2021 07:30:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-24-2021 07:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	“Other” is selected , however other specific item is blank. Please review and update as appropriate.
Feb-24-2021 07:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Transcription Error
Feb-24-2021 07:25:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-24-2021 07:25:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Transcription Error
Feb-24-2021 07:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	“Other” is selected , however other specific item is blank. Please review and update as appropriate.
Feb-24-2021 07:24:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Transcription Error
Feb-01-2021 14:24:51 (UTC-06:00) Central Time	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(US & Canada)				
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2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Feb-27-2021 15:27:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Feb-24-2021 07:30:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: office visit	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Mar-08-2021 16:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 2: Closed	Response satisfies query
Mar-08-2021 16:07:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Mar-08-2021 16:07:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO	New Information
Mar-02-2021 14:13:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 2: Reissued:Opened	Clin: Please consider updating to YES as subject was hospitalized for symptoms recorded on SOD CRF.
Feb-27-2021 15:29:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	added per dm
Feb-26-2021 07:50:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 2: Reissued:Opened	Clin: Upon further consideration, it was requested that the hospitalization data be entered into this visit.
Feb-24-2021 07:37:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	subject was not hospitalized for symptoms, subject was

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

				hospitalized for Motor vehicle accident.
Feb-23-2021 16:32:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 2: Opened	Clin: Upon further consideration, please restore previous hospitalization = Yes record and complete HOSP, RESP TX, ILL SEVERE, LAB CHEM, LAB HEM, VITALS COV, PULSE OX, OXYGEN, VASOPRESS, and IMAGING forms, as applicable.
Feb-03-2021 08:42:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Feb-02-2021 10:26:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-02-2021 10:26:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Transcription Error
Feb-02-2021 09:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clin: Was subject hospitalized due to potential COVID-19 illness or MVA? If not due to potential COVID-19 illness, it should not be recorded here.
Feb-01-2021 14:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: HOSPITALIZATION DETAILS - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-02-2021 10:28:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Deleted	Transcription Error
Feb-01-2021 14:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: HOSPITALIZATION DETAILS - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-27-2021 15:32:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Feb-02-2021 10:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-02-2021 10:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Feb-01-2021 14:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Feb-02-2021 10:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Feb-02-2021 10:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Feb-01-2021 14:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Feb-03-2021 08:44:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Feb-02-2021 10:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Feb-02-2021 10:28:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-02-2021 10:28:05 (UTC-06:00) Central Time	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

(US & Canada)				
Feb-02-2021 09:44:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clin: Was subject hospitalized due to potential COVID-19 illness or MVA? If not due to potential COVID-19 illness, it should not be recorded here.
Feb-01-2021 14:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Feb-02-2021 10:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Feb-02-2021 10:28:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Feb-01-2021 14:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO Discharge Date: Dec/25/2020	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Feb-27-2021 15:32:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Feb-27-2021 15:32:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Feb-27-2021 15:32:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Feb-27-2021 15:32:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO Discharge Date: Dec/25/2020	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Feb-27-2021 15:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-01-2021 14:27:31 (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-01-2021 14:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> motor vehicle accident Date of Diagnosis: Dec/23/2020	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-01-2021 14:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 3	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: ILLNESS DETAILS - SEVERE - Audit Trail

Form Version: 17-Jul-2020 21:55

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-01-2021 14:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-02-2021 10:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-02-2021 10:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Feb-01-2021 14:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE COVID-19 ILLNESS	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Feb-01-2021 14:34:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Feb-03-2021 08:44:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Closed	Response satisfies query
Feb-02-2021 10:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Applicable	Initial Entry
Feb-02-2021 10:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-02-2021 10:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Transcription Error
Feb-02-2021 09:45:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nicole Suzanne Caldwell (pfe.caldwn)	Query 1: Opened	Clin: Per CRF CRs Section 8.34, this CRF should only be completed if a participant had significant renal, hepatic or neurological

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

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				dysfunction as part of their potential COVID-19 illness. If not, please enter FORM LEVEL comment of Not Applicable.
Feb-01-2021 14:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<p>Data Entry: YES</p> <p><i>Diagnosis:</i> motor vehicle accident</p> <p>Start Date: Dec/23/2020</p> <p>Ongoing?: NO</p> <p>End Date: Dec/25/2020</p>	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-02-2021 10:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<p>Data Entry: Not Applicable</p>	Initial Entry
Feb-02-2021 10:31:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<p>Data Entry:</p>	Transcription Error
Feb-01-2021 14:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<p>Data Entry: 2</p>	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sponsor-Defined Identifier Not Done : Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

5.a Sponsor ID:

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sponsor-Defined Identifier Not Done : Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

			Lab Normal Range:	Not Done
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sponsor-Defined Identifier Not Done : Test:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.c Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

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(US & Canada)			Sponsor-Defined Identifier	Not Done
			:	e
			Test::	Not Done
				e
			Result::	Not Done
				e
			Not Done::	Not Done
				e
			Lab Normal Range:	Not Done
				e

5.d Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.e

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

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Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sponsor-Defined Identifier Not Done : Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sponsor-Defined Identifier Not Done : Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Lab Normal Range:	Not Done
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5.f Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> Sponsor-Defined Identifier Not Done : Test:: Not Done	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.g Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Feb-27-2021 15:52:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail
Form Version: 21-Aug-2020 02:51 **Form Status:**
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281296 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: unknown	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-28-2021 08:30:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_P X1 Result:: 9.5 Not Done::	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Lab Normal Range: Low unknown High unknown Unit g/dL	
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 1 Test:: Hemoglobin_PX1 Result:: 9.5 Not Done:: Lab Normal Range:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Feb-28-2021 08:30:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 9.5	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a LNMT

Date	Location	User	Value	Reason
Feb-28-2021 08:30:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Low unknown High unknown Unit g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_P X2 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

5.b Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.c

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes_PX3 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

5.c Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_PX5 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.d Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Platelets_PX5	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_P X7 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.e Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 608 tifier: Test:: Neutrophils_P X608 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.f Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 609 tifier: Test:: Eosinophils_P X609 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.g Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.h

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 612 tifier: Test:: Monocytes_PX 612 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.h Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Monocytes_PX612	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.i

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_PX 610 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.i Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Basophils_PX610	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.j

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_P X611 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.j Sponsor ID:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Feb-27-2021 15:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail
Form Version: 20-Feb-2021 02:18 **Form Status:**
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281296 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 20-Feb-2021 02:18

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: UNKNOWN	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/24/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_P X1 Result:: 9.1 Not Done::	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Lab Normal Range: <i>Low</i> UNKNOWN <i>High</i> UNKNOWN <i>Unit</i> g/dL	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 9.1	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: <i>Low</i> UNKNOWN <i>High</i> UNKNOWN <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(US & Canada)			Sponsor-Defined Identifier: Test:: Hematocrit_P X2 Result:: Not Done:: NOT DONE Lab Normal Range:
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes_PX3 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.c Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_PX 5 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.d Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Platelets_PX5	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_P X7 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.e Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 608 tifier: Test:: Neutrophils_P X608 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

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Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.f Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 609 tifier: Test:: Eosinophils_P X609 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

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Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.g Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.h

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 612 tifier: Test:: Monocytes_PX 612 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.h Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Monocytes_PX612	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.i

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_PX 610 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.i Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Basophils_PX610	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.j

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_P X611 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

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Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.j Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:18**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: UNKNOWN	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/25/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_P X1 Result:: 9.1 Not Done::	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:18**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

			Lab Normal Range: <i>Low</i> UNKNOWN <i>High</i> UNKNOWN <i>Unit</i> g/dL	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 9.1	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: <i>Low</i> UNKNOWN <i>High</i> UNKNOWN <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(US & Canada)			Sponsor-Defined Identifier: Test:: Hematocrit_P X2 Result:: Not Done:: NOT DONE Lab Normal Range:
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes_PX3 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

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Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.c Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_PX 5 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

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Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.d Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Platelets_PX5	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_PX7 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

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Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.e Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 608 tifier: Test:: Neutrophils_P X608 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

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Subject Initials: ---

Generated By: pfe.levisse

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5.f Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 609 tifier: Test:: Eosinophils_P X609 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.h

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 612 tifier: Test:: Monocytes_PX 612 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

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5.h Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Monocytes_PX612	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.i

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_PX 610 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.i Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Basophils_PX610	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

5.j

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_P X611 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:18

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.j Sponsor ID:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Feb-28-2021 11:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT DONE	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: VITAL SIGNS - COVID - Audit Trail

Form Version: 21-Aug-2020 02:50

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-28-2021 12:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date:

Date	Location	User	Value	Reason
Feb-28-2021 12:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-28-2021 12:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Record Identifier:: 1 Systolic:: 19 3 Diastolic:: 90 Respiratory Rate in respirations/ minute: 20 Heart Rate in beats/minute: 65	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-28-2021 12:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Mar-03-2021 12:54:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Elizabeth Chatburn (pfe.chatbe)	Query 1: Closed	confirmed not clinically significant
Mar-03-2021 09:40:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	Per PI, NCS
Mar-01-2021 00:55:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Reissued:Opened	DM: Please confirm reported value is clinically significant or not. If yes, please update AE. Thank you.
Feb-28-2021 12:13:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	PER MEDICAL RECORDS THIS IS SECONDARY TO PAIN

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Feb-28-2021 12:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 193 is outside of Normal Range 90 - 140.
Feb-28-2021 12:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 193	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Feb-28-2021 12:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 90	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Feb-28-2021 12:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 20	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Feb-28-2021 12:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 65	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Dec/23/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail

Form Version: 21-Aug-2020 02:51

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-28-2021 12:13:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date:

Date	Location	User	Value	Reason
Feb-28-2021 12:13:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-28-2021 12:13:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 96.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-28-2021 12:13:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Feb-28-2021 12:13:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: 96.0	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Feb-28-2021 12:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Feb-28-2021 12:13:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Feb-28-2021 12:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-28-2021 12:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-28-2021 12:01:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-28-2021 12:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-28-2021 12:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-28-2021 12:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020 **Form:** IMAGING - Audit Trail

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Feb-28-2021 12:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: OTHER <i>If other, specify:</i> PELVIS	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NORMAL	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: HEAD	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: CT SCAN	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NORMAL	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: OTHER <i>If other, specify:</i> SPINE	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: CT SCAN	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NORMAL	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NORMAL	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: OTHER <i>If other, specify:</i> LEFT WRIST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NORMAL	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/23/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/23/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: OTHER <i>If other, specify:</i> RIGHT SHOULDER	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Feb-28-2021 12:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NORMAL	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/22/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 14:51:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Feb/22/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-22-2021 14:51:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit
on Feb/22/2021**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:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-22-2021 14:51:43 (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-22-2021 14:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 14:58:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 14:51:43 (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.
Feb-22-2021 14:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: YES Date of Collection: Feb/22/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-22-2021 14:58:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BHPGK9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 14:58:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BHPGK9	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit
on Feb/22/2021

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: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.b

Date	Location	User	Value	Reason
Feb-22-2021 14:58:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BS8815	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 14:58:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BS8815	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-22-2021 15:01:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BS8876	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 15:01:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BS8876	Initial Entry

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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: 11281296

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-27-2020 10:56:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Oct/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-27-2020 10:56:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-27-2020 10:56:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: COMPLETED	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

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
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

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
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

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
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Form Created	

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

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
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 10:40:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Deleted	Being removed and added to COVID illness visit instead.
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Form Created	

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-02-2021 10:40:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Form Deleted	Being removed and added to COVID illness visit instead.
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

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
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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
Jan-04-2021 17:39:14 (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
Jan-04-2021 17:39:14 (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
Jan-18-2021 09:28:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 4: Closed	Response satisfies query
Jan-17-2021 17:46:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 5: Closed	Response satisfies query
Jan-15-2021 07:58:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 3: Closed	Response satisfies query
Jan-14-2021 22:42:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Closed	Response satisfies query
Jan-14-2021 22:09:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.
Jan-14-2021 18:27:03	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information

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Header Text: c4591001 Visit: Logs - Unscheduled Form Version: 22-Apr-2020 21:02 Site No: 1128 Subject No: 11281296 Generated By: pfe.levisse				
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History Form Status: Data Complete, Frozen Site Name: (1128) Ventavia Research Group Subject Initials: --- Generated Time (GMT): 29-Mar-2021 11:25				
(UTC-06:00) Central Time (US & Canada)				
Jan-14-2021 18:27:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-14-2021 18:27:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: MOTOR VEHICLE ACCIDENT	Changed Information
Jan-14-2021 18:25:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Query 5: Answered	updated
Jan-14-2021 18:24:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Query 2: Answered	updated
Jan-14-2021 18:19:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Query 3: Answered	updated
Jan-11-2021 18:10:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 5: Opened	ClinQuery: MOTOR VEHICLE ACCIDENT PAIN: When an MVA results in an injury, both the injury and the MVA should be recorded as AEs. For example, record 'motor vehicle accident' and 'pain' instead of 'pain due to MVA'. Please review and update appropriately.
Jan-10-2021	ACV0PFEINFP6000	Giselle	Query 4: Opened	Per report

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

10:51:03 (UTC-06:00) Central Time (US & Canada)		Castillo (pfe.castig19)		submitted to safety, the subject presented with "hemoglobin (HGB) of 9.5 on 23Dec2020 and 9.1" Kindly specify the units for the values provided in a FU report. Thank you.
Jan-10-2021 10:47:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 3: Opened	CLIN_ Per report, "Subject was complaining of severe right shoulder pain" If this was the injury as result of MVA, this additional separate event is missing on AE log. Please revise and update accordingly. Thank you.
Jan-08-2021 04:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Multiple concepts in the term MOTOR VEHICLE ACCIDENT PAIN. Split the term into MOTOR VEHICLE ACCIDENT and POST TRAUMATIC PAIN and submit separately. Thank you.
Jan-07-2021 20:37:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Opened	GPDClin: The previous term was concussion, with symptoms of soreness (head), nausea and vomiting. If the current term is used, please specify the site of pain and add other

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Visit: Logs - Unscheduled

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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				symptoms as AEs, and update SAE report with corresponding changes.
Jan-07-2021 18:24:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: MOTOR VEHICLE ACCIDENT PAIN	New Information
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: CONCUSSION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Dec/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-04-2021 17:39:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-04-2021 17:39:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO End Date Time: Dec/25/2020 UNK:UNK	Transcription Error
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For CONCUSSION End Date & Time 25/Nov/2020 UNK:UNK is before the Start Date & Time 23/Dec/2020 UNK:UNK.
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO End Date Time: Nov/25/2020 UNK:UNK	Initial Entry

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Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-05-2021 21:13:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Pijojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE CONCUSSION: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death ? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening?	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: AUTOMOBILE ACCIDENT	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-07-2021 18:25:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	New Information
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

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Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-08-2021 07:23:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 2: Closed	Response satisfies query
Feb-04-2021 20:25:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	site will submit a follow-up form to the safety database with outcome reported as RECOVERED/RESOLVED
Feb-04-2021 11:38:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 2: Reissued:Opened	SAE RECON 1: Per query response, please consider updating the safety database since outcome was reported as RECOVERED/RESOLVED WITH SEQUELAE. please submit a follow-up form
Feb-01-2021 13:02:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	RECOVERED/RESOLVED IS CORRECT
Jan-20-2021 01:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON:AER#2021005966,outcome was reported as RECOVERED/RESOLVED WITH SEQUELAE to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Jan-15-2021 12:03:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Closed	Response satisfies query
Jan-15-2021 09:31:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-15-2021 09:31:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: RECOVERED/RESOLVED	Changed Information

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Jan-07-2021 20:38:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Opened	GPDClin: Please clarify what sequelae is present. Otherwise, please change it to recovered/resolved.
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: RECOVERED/RESOLVED WITH SEQUELAE	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-04-2021 17:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-06-2021 05:04:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021005966	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Jan-14-2021 18:17:22 (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
Jan-14-2021 18:17:22 (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
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: severe right shoulder pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-14-2021 18:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-14-2021 18:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Dec/23/2020 UNK:UNK	Transcription Error
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For severe right shoulder pain Start Date 23/Jan/2021, is a future date relative to when it was entered on 14/Jan/2021. Please correct.
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/23/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> automotive accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT APPLICABLE	Initial Entry
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II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT RECOVERED/NOT RESOLVE D	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-14-2021 18:17:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Jan-14-2021 18:22:29 (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
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: post traumatic pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Dec/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO End Date Time: Jan/2/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

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Header Text: c4591001

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Subject No: 11281296

Generated By: pfe.levisse

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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
Jan-18-2021 05:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-15-2021 12:08:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE post traumatic pain: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-15-2021 12:08:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	New Information
Jan-14-2021 18:22:29 (UTC-06:00) Central Time	ACV0PFEINFP6000	Alma Sanchez	<p>Data Entry: NO</p>	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

(US & Canada)

(pfe.asanchez)

8. Is this adverse event the result of a study Medication Error?*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> automotive accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
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Subject No: 11281296

Generated By: pfe.levisse

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Form Status: Data Complete, Frozen

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Feb-08-2021 07:24:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Closed	Response satisfies query
Feb-04-2021 20:25:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	site will submit a follow-up form to the safety database with outcome reported as RECOVERED/RESOLVED
Feb-04-2021 11:39:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Reissued:Opened	SAE RECON 1: Per query response, please consider updating the safety database since outcome was reported as RECOVERED/RESOLVED WITH SEQUELAE. please submit a follow-up form
Feb-01-2021 13:02:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	RECOVERED/RESOLVED IS CORRECT
Jan-20-2021 01:57:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2021005966,outcome was reported as RECOVERED/RESOLVED WITH SEQUELAE to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-14-2021 18:22:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-18-2021 05:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021005966	Initial Entry

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Subject No: 11281296

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Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Jan-15-2021 09:39:21 (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
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: soreness to back of head	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Dec/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO End Date Time: Dec/25/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

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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
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-02-2021 07:54:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Close per site response
Feb-01-2021 13:05:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	COVID ILLNESS VISIT WAS NOT DONE, AS SUBJECT WAS HOSPITALIZED DUE TO A MOTOR VEHICLE ACCIDENT
Jan-22-2021 05:54:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	Per Prot Sect 8.1., COVID 19 listed symptom Soreness to back of head should have triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance and

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				captured only on the CRF SOD form. "[sudhip SDQ=109265]"
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> automotive accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

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Date	Location	User	Value	Reason
Jan-15-2021 09:39:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> NO	Initial Entry

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Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Deleted
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281296 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Category:

Date	Location	User	Value	Reason
Jan-15-2021 09:41:34 (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
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-02-2021 14:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Closed	Response satisfies query
Feb-01-2021 13:06:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	NO, PER PI THIS SYMPTOM WAS DUE TO A MOTOR VEHICLE ACCIDENT
Jan-23-2021 20:45:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Reissued:Opened	Clin: please confirm whether this symptom could have been due to COVID-19 or not.
Jan-21-2021 11:03:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	COVID illness visit was not done, due to subject being Hospitalized due to Motor Vehicle Accident.
Jan-20-2021 10:34:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: Since NAUSEA is one of the CDC-defined symptoms of COVID-19 (Prot Sect 8.1), please consider whether this symptom, could have been due to

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Deleted**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25***** THIS REPEATING FORM HAS BEEN DELETED *****

				COVID-19 and should have triggered a potential COVID illness visit
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: nausea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Dec/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO End Date Time: Dec/25/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?*If Yes, NOTIFY PFIZER IMMEDIATELY.**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?*If Yes, record the type of medication error on the Medication Error Log.*

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER If Other, specify: automotive accident	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-15-2021 09:42:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-15-2021 09:41:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Category:

Date	Location	User	Value	Reason
Jan-15-2021 09:44:52 (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
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-02-2021 14:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 2: Closed	Response satisfies query
Feb-02-2021 14:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Closed	Response satisfies query
Feb-01-2021 13:07:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	Query is ambiguous
Feb-01-2021 13:07:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	SITE WILL ADD, PER DM
Jan-23-2021 20:44:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 2: Opened	Clin: 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 if symptoms have resolved >4d
Jan-23-2021 20:43:46 (UTC-06:00) Central Time	ACV0PFEINFP6000	Salim Bouguermouh	Query 1: Reissued:Opened	Clin: Despite telehealth visit was

090177e196ae400b\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: 11281296 Generated By: pfe.levisse					Form: ADVERSE EVENT REPORT - eCRF Audit Trail History Form Status: Data Complete, Deleted Site Name: (1128) Ventavia Research Group Subject Initials: --- Generated Time (GMT): 29-Mar-2021 11:25				
*** THIS REPEATING FORM HAS BEEN DELETED ***									
(US & Canada)			(pfe.bogus)			not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured only on the SOD CRF form and a NASAL SWAB will not be collected			
Jan-21-2021 11:03:35 (UTC-06:00) Central Time (US & Canada)		ACV0PFEINFP6000		Jen Vasilio (pfe.jvasilio)		Query 1: Answered		COVID illness visit was not done, due to subject being Hospitalized due to Motor Vehicle Accident.	
Jan-20-2021 13:16:22 (UTC-06:00) Central Time (US & Canada)		ACV0PFEINFP6000		Erik Sundgaard (pfe.sundgaardea)		Query 1: Opened		Clin: Per Prot Sect 8.1., COVID-19 listed symptom VOMITING, should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance and captured only on the CRF SOD form	
Jan-20-2021 10:31:37 (UTC-06:00) Central Time (US & Canada)		ACV0PFEINFP6000		Salim Bouguermouh (pfe.bogus)		Query 1: Candidate		Clin: Per Prot Sect 8.1., COVID-19 listed symptom VOMITING, should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance and captured only on the CRF SOD form	
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)		ACV0PFEINFP6000		Alma Sanchez (pfe.asanchez)		Data Entry: vomiting		Initial Entry	
4. Start Date Time:									
Date		Location		User		Value		Reason	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

*** THIS REPEATING FORM HAS BEEN DELETED ***

Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Dec/23/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO End Date Time: Dec/25/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT RELATED If Not Related to study treatment(s), t	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1128) Ventavia Research Group

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*** THIS REPEATING FORM HAS BEEN DELETED ***

			his event is due to: OTHER <i>If Other, specify:</i> automotive accident	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-15-2021 09:44:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> NO	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Jan-15-2021 09:47:40 (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
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: anemia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Dec/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

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Form Status: Data Complete

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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
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-01-2021 14:18:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Closed	Response satisfies query
Feb-01-2021 13:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-01-2021 13:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> IRON DEFFICIENCY	Transcription Error
Jan-19-2021 22:20:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Opened	GPDClin: Please clarify which concomitant non-drug treatment caused anemia.
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT NON-DRUG TR	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

			EATMENT	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT RECOVERED/NOT RESOLVE D	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-15-2021 09:47:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS -
Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Oct-27-2020 10:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-27-2020 10:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-27-2020 10:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-27-2020 10:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-27-2020 10:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Influenza Vaccination	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-27-2020 10:56:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Oct/22/2020	Initial Entry

090177e196ae400b\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: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-31-2020 15:13:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Dec/30/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

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
Dec-31-2020 15:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-31-2020 15:14:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-31-2020 15:14:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

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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I. Date of Visit

Date	Location	User	Value	Reason
Jan-06-2021 17:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/4/2021	New Information
Jan-06-2021 17:07:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/6/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-06-2021 17:07:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: OBTAINED Date Written Consent Obtained Jan/4/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

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
Jan-06-2021 17:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/4/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-06-2021 17:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-06-2021 17:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: COMPLETED	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form Version:** 10-Dec-2020 02:23**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:**

Date	Location	User	Value	Reason
Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Choriogonadotropin Beta_PX113 Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-06-2021 17:09:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done::	Transcription Error
Jan-06-2021 17:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-06-2021 17:09:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Jan-06-2021 17:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-06-2021 17:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
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090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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-06-2021 17:09:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Not Applicable	Initial Entry
Jan-06-2021 17:09:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry:	Transcription Error
Jan-06-2021 17:08:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NOT DONE	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-06-2021 17:09:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-06-2021 17:09:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-07-2021 09:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-07-2021 07:53:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-06-2021 17:09:44 (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.
Jan-06-2021 17:09:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES Date of Collection: Jan/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-07-2021 09:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rogomez1)	Data Entry: Sample ID: BHXN7H	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Jan-07-2021 09:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BHXN7H	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-07-2021 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BS7NJ3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-07-2021 10:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BS7NJ3	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-07-2021 10:41:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BS7ND5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-07-2021 10:41:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BS7ND5	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-06-2021 17:09:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-06-2021 17:09:58 (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
Jan-07-2021 10:43:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-07-2021 07:53:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-06-2021 17:09:58 (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.
Jan-06-2021 17:09:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES Date of Collection: Jan/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-07-2021 10:43:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rogomez1)	Data Entry: Sample ID: BHPFX0	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Jan-07-2021 10:43:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BHPFX0	Initial Entry

Header Text: c4591001**Visit:** V101_VAX3**Form Version:** 10-Dec-2020 02:26**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** VACCINATION - 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. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-06-2021 17:10:38 (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
Jan-06-2021 17:10:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-06-2021 17:10:38 (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
Jan-06-2021 17:10:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Jan/4/2021 13:07	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-06-2021 17:10:38 (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
Jan-06-2021 17:10:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Jan-06-2021 17:10:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Jan-06-2021 17:10:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-06-2021 17:10:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-06-2021 17:10:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-06-2021 17:10:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

090177e196ae400b\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: 11281296

Generated By: pfe.levissc

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
Dec-31-2020 15:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Dec/30/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-31-2020 15:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

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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I. Date of Visit

Date	Location	User	Value	Reason
Jan-25-2021 09:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Jan/25/2021	Initial Entry

Header Text: c4591001**Visit:** V102_VAX4**Form Version:** 10-Dec-2020 02:23**Site No:** 1128**Subject No:** 11281296**Generated By:** pfe.levisse**Form:** LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:**

Date	Location	User	Value	Reason
Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

			Not Done::	Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-25-2021 09:47:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-25-2021 09:48:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-25-2021 09:48:07 (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
Jan-25-2021 16:42:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-25-2021 10:34:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-25-2021 09:48:07 (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.
Jan-25-2021 09:48:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES Date of Collection: Jan/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 16:42:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BHPGB8	Initial Entry

5.a Sample ID

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Jan-25-2021 16:42:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: BHPGB8	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: VACCINATION - 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. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-25-2021 10:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-25-2021 10:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-25-2021 10:59:15 (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
Jan-25-2021 10:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Jan/25/2021 10:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-25-2021 10:59:15 (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
Jan-25-2021 10:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Jan-25-2021 10:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
---	-----------------	-------------------------	-------------------------------------	---------------

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-25-2021 10:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-25-2021 10:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-25-2021 10:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-25-2021 10:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281296

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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I. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 14:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Closed	Response satisfies query
Feb-23-2021 12:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	added date
Feb-23-2021 05:40:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of visit at visit 103.
Feb-22-2021 16:52:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Feb/22/2021	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281296

Generated By: pfe.levisse

Form: CONTACT OUTCOME - 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. Contact Type:

Date	Location	User	Value	Reason
Feb-22-2021 16:52:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-22-2021 16:52:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Date of Contact: Feb/22/2021	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281296**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**I. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-25-2021 04:20:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Adarsh Prabhu (pfe.prabha11)	Query 3: Clo sed	Incorrect query
Feb-25-2021 03:47:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Op ened	DMW7444620;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-24-2021 20:18:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Clo sed	Auto closed by Validation Check: VC_DS001_30
Feb-24-2021 07:41:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Transcription Error
Feb-24-2021 07:41:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry : Feb/2 2/202 1	Transcription Error
Feb-24-2021 06:26:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Adarsh Prabhu (pfe.prabha11)	Query 1: Clo sed	Incorrect query
Feb-24-2021 06:12:50 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Op ened	DMW7403020;Status on the Disposition - Treatment form is COMPLETED at FURTHER_VACCINATION_EOT visit, but Date is different than

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281296

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Canada)				Visit V103 Date. Please review and update as appropriate.
Feb-24-2021 05:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7402987;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-23-2021 12:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry : Feb/20/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-23-2021 12:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-23-2021 12:01:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: COMPLETED	Initial Entry

090177e196ae400b\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281296

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-27-2020 10:56:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-08-2020 13:52:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-08-2020 13:47:49 (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
Oct-27-2020 10:56:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/27/2020	Initial Entry
Sep-08-2020 13:52:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/8/2020	Initial Entry
Sep-08-2020 13:47:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/8/2020	Initial Entry

090177e196ae400b\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: 11281296

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

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Oct-31-2020 11:27:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Click Here to Enable	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

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: 11281359

Subject Initials: ---

Generated By: pfe.levissc

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	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/15/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[11281359]
2.	Birth Date:	(b) (6)/1996
3.	Sex:	MALE
4.	Ethnicity:	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: 11281359

Generated By: pfe.levissc

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/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1128

Subject No: 11281359

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	---	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	---	-------------------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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	Sep/15/2020
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: 11281359

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergic rhinitis]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

Form: HIV STATUS

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](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1128

Subject No: 11281359

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:	Sep/15/2020
2.	Weight:	[166.4]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[26.9]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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 :	Sep/15/2020
2.	Randomization Number:	[90289]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

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: Sep/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHXNDS]
5.b	Sample ID	[BPR3SB]
5.c	Sample ID	[BPR3L2]

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisc

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: Sep/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5KTH]
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090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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:	Sep/15/2020 11:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	--	---

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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	Oct/6/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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:	Oct/6/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[96.6]
	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: 11281359

Generated By: pfe.lewissc

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: Oct/6/2020
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	[BHXN18]
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090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281359

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:	Oct/6/2020 10:56
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

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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	Nov/5/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

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: Nov/5/2020
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	[BHXNMR]
5.b	Sample ID	[BJ6SSC]
5.c	Sample ID	[BJ6SXX]

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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	[]
----	-----------	-----

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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	[]
----	-----------	-----

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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	[]
----	-----------	-----

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Jan/26/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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	Jan/26/2021
2.	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 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Jan/26/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/26/2021
2.	Date of First Symptom Started:	Jan/22/2021
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Jan/26/2021

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Jan/26/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.a	Symptoms - Other Text:	[Nasal Congestion]
-----	------------------------	--------------------

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: 11281359

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 **Form:** MICROBIOLOGY SPECIMEN
on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)
[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

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Jan/26/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Jan/31/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Site shipping swab kit to subject on 27JAN2021]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV52422]
-----	-----------	-----------

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Jan/26/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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	SITE	Comments
2.	Sample Type	NASAL_SWAB	Comments
3.	Sample Collected?	NO	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject to collect self swab at home]	Comments

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Jan/26/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281359**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25**eCRF Audit Trail History****Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

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: 11281359

Subject Initials: ---

Generated By: pfe.levisc

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Jan/26/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Respiratory Treatment

1.	What is the treatment Identifier?	[]
2.	Concomitant Non-drug Treatment Pre-specified:	
3.	Treatment:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Jan/26/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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 **Form:** ILLNESS DETAILS - SEVERE
on Jan/26/2021

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

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: 15-Sep-2020 21:51

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

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 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Jan/26/2021

Form Version: 15-Sep-2020 21:51

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

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

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

#	Category for Lab Test	Vendor Name (DE RIVED)	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 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/26/2021

Form Version: 15-Sep-2020 21:55

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 15-Sep-2020 21:52

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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 **Form:** VITAL SIGNS - COVID
on Jan/26/2021

Form Version: 15-Sep-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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 **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Jan/26/2021

Form Version: 15-Sep-2020 21:54

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Vital Signs

1.	Date:	//
----	-------	----

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: 11281359

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 **Form:** OXYGENATION PARAMETERS
on Jan/26/2021

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

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: 11281359

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 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Jan/26/2021

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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?	

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (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: 11281359

Subject Initials: ---

Generated By: pfe.levisc

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 **Form:** IMAGING
on Jan/26/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

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 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Mar/01/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Mar/1/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Visit on Mar/01/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

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: Mar/1/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BS888H]
5.b	Sample ID	[BS8852]
5.c	Sample ID	[BHPG24]

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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: 11281359

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	[]
----	-----------	-----

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: 11281359

Subject Initials: ---

Generated By: pfe.levissc

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: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Unplanned Assessments

1.	Assessments	
----	-------------	--

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: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Left Supraclavicular Adenopathy	Oct/7/2020 UNK:UNK	NO End Date Time: Oct/8/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Left Arm injection site Pain	Oct/7/2020 11:00	NO End Date Time: Oct/8/2020 UNK:UNK	Repeating Pages

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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)	[Left Supraclavicular Adenopathy]
4.	Start Date Time:	Oct/7/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/8/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left Arm injection site Pain]
4.	Start Date Time:	Oct/7/2020 11:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/8/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

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	[]

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (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: 11281359

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

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

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: 11281359

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.	Date:	//

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (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: 11281359

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

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?	

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (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: 11281359

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

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: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

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: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

eCRF Audit Trail History

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Nov/5/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 11281359

Subject Initials: ---

Generated By: pfe.levissc

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: 11281359

Subject Initials: ---

Generated By: pfe.levissc

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: 11281359

Subject Initials: ---

Generated By: pfe.lewissc

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?	

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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: 11281359

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: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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	[]
----	-----------	-----

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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	[]
----	-----------	-----

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Disposition - Follow-Up

1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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	Dec/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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

eCRF Audit Trail History

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/22/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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	FOLLOW-UP
2.	Subject Status Date	Nov/5/2020

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: 11281359

Subject Initials: ---

Generated By: pfe.levissc

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: 11281359

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 17:08:38 (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.

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

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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Item	Date	User	Comment
Form	Sep-25-2020 12:16:19 (UTC-06:00) Central Time (US & Canada)	Burt Ray (pfe.bray2)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
5	Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6	Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
7	Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
8	Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
9	Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021 **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: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-26-2021 17:19:22 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
Form	Jan-26-2021 17:19:15 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

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: 11281359

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-26-2021 17:19:22 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
1	Jan-26-2021 17:19:15 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

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: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Jan-26-2021 17:19:22 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
2	Jan-26-2021 17:19:15 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

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: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Jan-26-2021 17:19:22 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
3	Jan-26-2021 17:19:15 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

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: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Jan-26-2021 17:19:22 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	
4	Jan-26-2021 17:19:15 (UTC-06:00) Central Time (US & Canada)	Erin McLeod (pfe.emcLeod)	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: 11281359

Subject Initials: ---

Generated By: pfe.levisse

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 17:08:38 (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.

Erin McLeod	N/A	Mar-01-2021 15:40:34 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Feb-24-2021 14:29:09 (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.

Reyna Gomez	N/A	Feb-03-2021 15:43:22 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Mark Koch	Approved	Jan-31-2021 12:07:54 (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.

Erin McLeod	N/A	Jan-26-2021 17:17:33 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Dec-28-2020 11:01:44 (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	Dec-17-2020 11:43:13 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Nov-06-2020 17:44:13 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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
Sep-25-2020 12:15:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 08 SEP 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Sep-25-2020 12:15:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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
Sep-25-2020 12:15:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: OBTAINED Date Written Consent Obtained Sep/15/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281359

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
Sep-25-2020 12:15:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281359	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-25-2020 12:14:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1996	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-25-2020 12:15:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-25-2020 12:15:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: HISPANIC OR LATINO(A) OR O F SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-25-2020 12:15:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: WHITE	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisc

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
Oct-01-2020 23:48:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Malla Reddy Chevella (pfe.chevem01)	Query 1: Closed	Response satisfies query
Oct-01-2020 17:31:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Query 1: Answered	Swab has been entered
Sep-30-2020 00:28:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: Kindly review and complete 'Nasal Swab form' at this visit. Thank you.
Sep-25-2020 12:16:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/15/2020	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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
Sep-25-2020 12:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-25-2020 12:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-25-2020 12:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: COMPLETED	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

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
Sep-25-2020 12:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History Term: allergic rhinitis Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-25-2020 12:18:09 (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
Sep-25-2020 12:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: allergic rhinitis	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 12:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2015	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-25-2020 12:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

Form: HIV STATUS - 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 - What is the subject HIV status?

Date	Location	User	Value	Reason
Sep-29-2020 16:31:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 15-Sep-2020 21:56**Site No:** 1128**Subject No:** 11281359**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[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 16:31:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-29-2020 16:31:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Sep/15/2020	Transcription Error
Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital signs Date 12/Sep/2020 is not same as Date of Visit 15/Sep/2020. Please review and update as appropriate or clarify.
Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/12/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 166.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1128

Subject No: 11281359

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

Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 66.0	Initial Entry
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5. Unit:

Date	Location	User	Value	Reason
Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 26.9	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Record Identifier:: 1 Temperature: 97.2 Temperature Unit: F Temperature Loca ORAL CAVI tion:: TY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 97.2	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1128

Subject No: 11281359

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

7.a Unit:

Date	Location	User	Value	Reason
Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-25-2020 12:25:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

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
Sep-25-2020 12:26:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/15/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-25-2020 12:26:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 90289	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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
Sep-28-2020 16:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-28-2020 16:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-28-2020 16:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-28-2020 16:37:30 (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.
Sep-28-2020 16:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-28-2020 16:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sample ID: BHXNDS	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 16:37:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> BHXNDS	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-28-2020 16:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Sample ID: BPR3SB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 16:38:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> BPR3SB	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-28-2020 16:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> Sample ID: BPR3L2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-28-2020 16:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> BPR3L2	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281359**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin**

Date	Location	User	Value	Reason
Oct-01-2020 17:23:12 (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-01-2020 17:23:12 (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
Oct-01-2020 17:31:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 17:23:12 (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-01-2020 17:23:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 17:31:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry: Sample ID: BP5KTH	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 20:34:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_06
Oct-05-2020 07:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW4871836;The barcode BP5KTH is recorded for two subjects 11281359 and 11281354, Please review and update as appropriate.
Oct-01-2020 17:31:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mercedes Livingston (pfe.mlivingston)	Data Entry : BP5K TH	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281359

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
Sep-25-2020 12:27:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-25-2020 12:27:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-25-2020 12:27:29 (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
Sep-25-2020 12:27:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/15/2020 11:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-25-2020 12:27:29 (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
Sep-25-2020 12:27:29 (UTC-06:00) Central	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: LEFT	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281359

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

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Sep-25-2020 12:27:29 (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
Sep-25-2020 12:27:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-25-2020 12:27:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281359

Generated By: pfe.levissc

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
Sep-25-2020 12:33:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO - REACTOGENICITY E-DIARY NOT 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: 11281359

Generated By: pfe.levissc

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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1. Date of Visit

Date	Location	User	Value	Reason
Oct-06-2020 13:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Oct/6/2020	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281359

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

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1. Date:

Date	Location	User	Value	Reason
Oct-06-2020 13:50:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Oct/6/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-06-2020 13:51:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Record Identifier:: 1 Temperature: 96.6 Temperature Unit: F Temperature Loca ORAL CAVI tion:: TY	Initial Entry
Oct-06-2020 13:50:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Record Identifier:: 1 Temperature: 96.6 Temperature Unit: Temperature Location::	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-06-2020 13:50:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-07-2020 11:14:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 1: Closed	Response satisfies query
Oct-06-2020 13:54:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Query 1: Answered	Per PI not of clinical significance

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

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

Oct-06-2020 13:51:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.6 F is outside of Normal Range 97 - 99.5 F.
Oct-06-2020 13:50:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: 96.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-06-2020 13:51:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-06-2020 13:51:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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-06-2020 13:54:20 (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-06-2020 13:54:20 (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
Oct-07-2020 08:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-07-2020 08:31:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-06-2020 13:54:20 (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-06-2020 13:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: YES Date of Collection: Oct/6/2020	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

5.a

Date	Location	User	Value	Reason
Oct-07-2020 08:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BHXN18	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 08:49:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: BHXN18	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281359

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
Oct-06-2020 13:51:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-06-2020 13:51:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-06-2020 13:51:50 (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
Oct-06-2020 13:51:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Oct/6/2020 10:56	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-06-2020 13:51:50 (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
Oct-06-2020 13:51:50 (UTC-06:00) Central	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: LEFT	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281359

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

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Oct-06-2020 13:51:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-06-2020 13:51:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Oct-06-2020 13:51:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

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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1. Date of Visit

Date	Location	User	Value	Reason
Nov-05-2020 11:24:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Nov/5/2020	Initial Entry

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:** 11281359**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-05-2020 11:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-05-2020 11:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-05-2020 12:08:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-05-2020 11:24:53 (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.
Nov-05-2020 11:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: YES Date of Collection: Nov/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-05-2020 12:08:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sample ID: BHXNMR	Initial Entry

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: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 12:08:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> BHXNMR	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-05-2020 12:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Sample ID: BJ6SSC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 12:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> BJ6SSC	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-05-2020 12:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Sample ID: BJ6SXN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-05-2020 12:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> BJ6SXN	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/26/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 04:34:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pankaj Bhoir (pfe.bhoirp02)	Query 1: Closed	Details are entered on ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF form.
Feb-16-2021 01:07:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Reissued:Candidate	PDQ RQ1: Thank you for the response, please update the details once available else clarify.
Feb-12-2021 18:37:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	once sample received the barcode will be added
Feb-11-2021 07:05:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Reissued:Opened	PDQ: Per comment on self swab "Site shipping swab kit to subject on 27JAN2021". Kindly provide swab details once data available.
Feb-03-2021 23:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Reissued:Candidate	PDQ : As Per site response -once sample received the barcode will be added
Feb-03-2021 13:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	once sample received the barcode will be added
Feb-03-2021 02:07:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 1: Reissued:Opened	PDQ: Per comment on self swab "Site shipping swab kit to subject on

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/26/2021**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281359**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

				27JAN2021". Kindly provide swab details once data available.
Feb-01-2021 00:01:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Reissued:Candidate	PDQ : As Per site response -once sample received the barcode will be added
Jan-29-2021 16:31:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	once sample received the barcode will be added
Jan-27-2021 01:04:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Annam Sireesha (pfe.sireea)	Query 1: Opened	PDQ: Per comment on self swab "Site shipping swab kit to subject on 27JAN2021". Kindly provide swab details once data available.
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-26-2021 17:17:32 (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.
Jan-26-2021 17:17:32 (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.
Jan-26-2021 17:17:32	ACV0PFEINFP6000	Erin McLeod	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/26/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central
Time (US & Canada)

(pfe.emcLeod) Jan/26/2021

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-26-2021 17:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281359**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Jan/26/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Jan/22/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Mar-01-2021 15:40:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO Date of Last Symptom Resolved: Jan/26/2021	New Information
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00	ACV0PFEINFP6000	Erin McLeod	Data Entry:	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281359**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25(UTC-06:00) Central
Time (US & Canada)

(pfe.emcLeod)

FEVER

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms NEW OR INCREA : SED COUGH Symptom YES Present:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEW OR INCREASED COUG H	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sympto NEW OR INCREAS ms: ED SHORTNESS OF BREATH	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Symptom Present: NO	
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4.c Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

4.e

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptom NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281359**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25**4.f Symptoms:**

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: DIARRHE A Symptom Present YES :	Initial Entry
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4.h Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms: VOMITIN G Symptom Present NO :	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 17:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-26-2021 17:18:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Symptoms - Other: Nasal Congestion	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-26-2021 17:18:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Nasal Congestion	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
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090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/26/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry
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7. Test Result:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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-26-2021 17:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 17:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-02-2021 15:38:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe.riddlj)	Query 2: Closed	Response satisfies query
Mar-02-2021 10:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 2: Answered	data entered is correct, please note the subject reported COVID sx on 26JAN21 site mailed swab kit on 27JAN21 and subject completed the swab 31JAN21.
Mar-01-2021 15:40:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate.

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281359**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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

Feb-03-2021 15:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 15:43:22 (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.
Feb-03-2021 15:43:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe rgomez1)	Data Entry: YES Date of Collection: Jan/31/2021	New Information
Jan-26-2021 17:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	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
Jan-26-2021 17:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Site shipping swab kit to subject on 27JAN2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-03-2021 15:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: CV52422	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-03-2021 15:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: CV52422	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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-26-2021 17:19:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry
Jan-26-2021 17:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u>	Initial Entry
Jan-26-2021 17:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-26-2021 17:19:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry
Jan-26-2021 17:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u>	Initial Entry
Jan-26-2021 17:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-26-2021 17:19:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u> NO	Initial Entry
Jan-26-2021 17:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	<u>Data Entry:</u>	Initial Entry
Jan-26-2021 17:19:15	ACV0PFEINFP6000	Erin McLeod	<u>Data Entry:</u>	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/26/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)

(pfe.emcLeod)

Not Applicable

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Subject to collect self swab at home	Initial Entry
Jan-26-2021 17:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry:	Initial Entry
Jan-26-2021 17:19:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/26/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/26/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281359**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
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/26/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/26/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281359**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: TELEPHONE CONSULTATIO N	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.f

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or NO Contacts:	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/26/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Jan-26-2021 17:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Jan/26/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

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
Jan-26-2021 17:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jan-26-2021 17:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 17:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: 1	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/01/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-01-2021 15:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Mar/1/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-01-2021 15:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: COVID_A1	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/01/2021**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:** 11281359**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-01-2021 15:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-01-2021 15:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-01-2021 16:44:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 15:43:46 (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.
Mar-01-2021 15:43:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: YES Date of Collection: Mar/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-01-2021 16:44:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	Data Entry: Sample ID: BS888H	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/01/2021

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: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.a Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 16:44:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	<u>Data Entry:</u> BS888H	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-01-2021 16:45:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	<u>Data Entry:</u> Sample ID: BS8852	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 16:45:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	<u>Data Entry:</u> BS8852	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-01-2021 16:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	<u>Data Entry:</u> Sample ID: BHPG24	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-01-2021 16:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Reyna Gomez (pfe.rgomez1)	<u>Data Entry:</u> BHPG24	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

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
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

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
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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
Oct-16-2020 16:11:52 (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
Oct-16-2020 16:11:52 (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
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Left Supraclavicular Adenopathy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Oct/7/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-18-2020 08:35:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 2: Closed	Response satisfies query
Dec-17-2020 11:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-17-2020 11:43:13 (UTC-06:00) Central	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	New Information

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)			End Date Time: Oct/8/2020 UNK:UNK	
Dec-14-2020 05:46:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 2: Opened	Clin: Please confirm if this AE is still ongoing
Nov-10-2020 03:38:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Response satisfies query
Nov-09-2020 18:00:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	event is ongoing
Nov-09-2020 09:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: Please confirm if this AE is still ongoing
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-17-2020 11:49:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-17-2020 11:49:13 (UTC-06:00) Central	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> RECOVERED/RESOLVED	New Information

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281359 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

Time (US & Canada)				
Dec-17-2020 11:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Left Supraclavicular Adenopathy: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-16-2020 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 16:35:08 (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
Oct-16-2020 16:35:08 (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
Oct-25-2020 17:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Closed	Response satisfies query
Oct-25-2020 16:02:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-25-2020 16:02:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Left Arm injection site Pain	Transcription Error
Oct-19-2020 12:09:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Opened	GPDClin: Please clarify if this was injection site pain/soreness. If yes, please modify the term accordingly. If the soreness was in the arm beyond deltoid, keep the current term.
Oct-16-2020 16:35:08	ACV0PFEINFP6000	April Beech	Data Entry:	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)		(pfe.abeech)	Left Arm Pain	
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4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: Oct/7/2020 11:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-03-2021 11:45:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (pfe.liaukf)	Query 1: Closed	Response satisfies query
Mar-03-2021 09:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-03-2021 09:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO End Date Time: Oct/8/2020 UNK:UNK	Transcription Error
Mar-02-2021 06:45:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (pfe.liaukf)	Query 1: Opened	GPD CLIN: Please confirm if the subject's AE is still ongoing; else provide end date as applicable.
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: 1	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281359

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-08-2021 16:05:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-08-2021 16:05:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RECOVERED/RESOLVED	New Information
Mar-03-2021 09:04:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Left Arm injection site Pain: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-16-2020 16:35:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	April Beech (pfe.abeech)	Data Entry: NO	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-05-2020 11:25:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: Nov/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-05-2020 11:25:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-05-2020 11:25:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jessica Mendoza (pfe.jmendoza)	Data Entry: COMPLETED	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-24-2020 15:01:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/22/2020	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1128

Subject No: 11281359

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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I. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Dec-24-2020 15:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-24-2020 15:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-24-2020 15:01:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Participant is willing to return fo r Vaccination 3 Participant is: eligible and NOT confirmed t o have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

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
Dec-24-2020 15:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/22/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-24-2020 15:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281359

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

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1. Subject Status

Date	Location	User	Value	Reason
Nov-05-2020 11:25:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-25-2020 12:26:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-25-2020 12:16:54 (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
Nov-05-2020 11:25:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/5/2020	Initial Entry
Sep-25-2020 12:26:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry
Sep-25-2020 12:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281359

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-06-2020 15:16:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae4004\Final\Final On: 01-Apr-2021 05:28 (GMT)