

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[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	Form: MAIN INFORMED CONSENT
Visit: COHORT_SELECTION	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1085) Ventavia Research Group
Site No: 1085	Subject Initials: ---
Subject No: 10851018	Generated Time (GMT): 29-Mar-2021 10:22
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Informed Consent

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

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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Demography

1.	Subject ID	[10851018]
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:	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1085**Subject No:** 10851018**Generated By:** pfe.levissc**Form:** INCLUSION/EXCLUSION CRITERIA**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1085) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22**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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

	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
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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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
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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition - Screening

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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Left Ventricle Hypertrophy]
	Start Date:	May/UNK/2020
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Migraines]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tubal Ligation]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/1/2020
2.	Weight:	[230.0]
3.	Unit:	LB
4.	Height:	[67.0]
5.	Unit:	in
6.	Body Mass Index:	[36.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[96.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/1/2020
2.	Randomization Number:	[41321]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/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	[BP5BT5]
5.b	Sample ID	[BP5BT6]
5.c	Sample ID	[BP5BT7]
5.d	Sample ID	[BLD1V0]
5.e	Sample ID	[BLD1V1]

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/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	[BP5BSZ]
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[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/1/2020 11:56
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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[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: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/22/2020
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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[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?	YES Ongoing? NO Stop Date: Aug/7/2020

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02 51

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/22/2020
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Vital Signs Details

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

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1085**Subject No:** 10851018**Generated By:** pfe.levissc**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1085) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

[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 Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/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	[BMD7R4]
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[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/22/2020 11:21
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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/21/2020
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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
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	[BP9N66]
5.b	Sample ID	[BNVT8N]
5.c	Sample ID	[BNVT8P]

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BLD2GR]
5.b	Sample ID	[BLD2GS]
5.c	Sample ID	[BR6WJX]

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Nov/09/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/9/2020
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 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Nov/09/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/9/2020
2.	Date of First Symptom Started:	Nov/7/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/10/2020

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?	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?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Symptoms - Other

5.	Symptoms - Other Text:	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	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 **Form:** MICROBIOLOGY SPECIMEN
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/09/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[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/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	[CV10949]
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Nov/09/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ []
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Nov/09/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:22[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:	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?	NO
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	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 **Form:** RESPIRATORY TREATMENT
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[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	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	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	
					Not Done	Not Done	Not Done	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)
[Form Comments](#)
[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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

5.b	Sponsor ID:	Not Done _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

5.c	Sponsor ID:	Not Done _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

5.d	Sponsor ID:	Not Done _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

5.e	Sponsor ID:	Not Done _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

5.f	Sponsor ID:	Not Done _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

5.g	Sponsor ID:	Not Done _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	Category for Lab Test	Vendor Name (DERIVED)	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	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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

Laboratory Data Hematology

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:	Hemoglobin_PX1	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

5.b	Sponsor ID:	Not Done _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

5.c	Sponsor ID:	Not Done _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

5.d	Sponsor ID:	Not Done _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

5.e	Sponsor ID:	Not Done _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

5.f	Sponsor ID:	Not Done _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

5.g	Sponsor ID:	Not Done _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

5.h	Sponsor ID:	Not Done _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

5.i	Sponsor ID:	Not Done _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

5.j	Sponsor ID:	Not Done _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____ []	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Done	Not Done	Not Done	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	Systolic:	Not Done _____ []	Comments
	Diastolic:	Not Done _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Done _____ []	Comments
	Heart Rate in beats/minute:	Not Done _____ []	Comments

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	Date:	Vital Signs Details		Form Instance
1.	Not Done	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Done	Not Done	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	SPO2 Pulse Oximetry %	Not Done _____ []	Comments

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Nov/09/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Imaging

1.	Date of Assessment:	Not Done _____ //	Comments
2.	Location of Assessment:	Not Done _____	Comments
3.	Type of Imaging Exam:	Not Done _____	Comments
4.	Assessment:	Not Done _____	Comments

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/08/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/8/2020
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/08/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/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	[BNZL2F]
5.b	Sample ID	[BS7WBP]
5.c	Sample ID	[BS7WBR]

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/08/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/08/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/08/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/8/2020 Contact Outcome: VISIT NOT ARRANGED, REACTION NO LONGER PRESENT
3.	Comments:	[Reaction resolved the afternoon of 08Aug2020 per subject.]

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Sep/21/2020
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: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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?:	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[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	[]

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[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:	//

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	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: 1085

Subject No: 10851018

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[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?	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	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: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[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?	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

#	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: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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:	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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?	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085 **Site Name:** (1085) Ventavia Research Group
Subject No: 10851018 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:22

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/11/2021
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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[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
----	---	--

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/11/2021
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: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: DEATH DETAILS CODED

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Form Comments](#)

[eCRF Audit Trail History](#)

Death Details

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	Comments
----	---	-------------------------------	--------------------------

Cause of Death

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ []

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: SUBJECT STATUS

Form Status: Data Complete, Queries, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/21/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-22-2020 12:38:04 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Aug-22-2020 12:38:04 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2	Aug-22-2020 12:38:04 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
3	Aug-22-2020 12:38:04 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
4	Aug-22-2020 12:38:04 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5	Aug-22-2020 12:38:04 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-22-2020 12:38:04 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-22-2020 12:38:04 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-22-2020 12:38:04 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5	Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
6	Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
7	Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
8	Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
9	Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/09/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 15:57:44 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Telehealth visit <hr/> Not Done

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 15:57:44 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Telehealth visit <hr/> Not Done

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 15:57:44 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Telehealth visit <hr/> Not Done

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 15:57:44 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Telehealth visit <hr/> Not Done

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 15:57:44 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Telehealth visit <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5	Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
6	Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
3	Nov-11-2020 16:06:30 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	
3	Nov-10-2020 15:58:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 15:59:07 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 15:59:07 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 15:59:07 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 15:59:07 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 15:59:07 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

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Site Name: (1085) Ventavia Research Group

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[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

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[Back to Form](#)

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[Back to Form](#)

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Subject No: 10851018

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

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Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

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Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

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Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

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Subject Initials: ---

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[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1085

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[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

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Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
5 f	Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

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Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

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Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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Subject No: 10851018

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

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Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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Subject No: 10851018

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

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Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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Form Version: 30-Jul-2020 21:28

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

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Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5 f	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5 h	Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 16:01:10 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
on Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 16:01:25 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
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[Back to Form](#)

Item	Date	User	Comment
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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-10-2020 16:01:25 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 16:01:47 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 16:01:47 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1085

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Subject No: 10851018

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[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

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[Back to Form](#)

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3	Nov-10-2020 16:01:47 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 16:02:07 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 16:02:07 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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Form Version: 06-Jul-2020 21:55

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 16:02:07 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

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Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

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Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
5	Nov-10-2020 16:02:07 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

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Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

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Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
6	Nov-10-2020 16:02:07 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 16:02:28 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

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Form Version: 06-Jul-2020 21:53

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 16:02:28 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Done

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-01-2021 15:17:30 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Mar-01-2021 15:17:30 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-01-2021 15:17:46 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
1	Mar-01-2021 15:17:46 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Chyann Stewart	N/A	Mar-01-2021 15:17:15 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Gregory Fuller	Approved	Dec-10-2020 15:55:18 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, GregoryFuller, 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.

Claudia Alonzo	N/A	Dec-08-2020 10:23:29 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Gregory Fuller	Approved	Nov-17-2020 14:06:58 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, GregoryFuller, 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.

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.leivissc

Generated Time (GMT): 29-Mar-2021 10:22

Banika Ervin	N/A	Nov-10-2020 15:56:05 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Gregory Fuller	Approved	Oct-12-2020 14:05:11 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:
By my dated signature below, I, GregoryFuller, 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.

Angi Cox	N/A	Sep-21-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Gregory Fuller	Approved	Sep-11-2020 16:13:37 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:
By my dated signature below, I, GregoryFuller, 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.

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-01-2020 16:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-01-2020 16:52:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: OBTAINED Date Written Consent Obtained Aug/1/2020	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Subject ID

Date	Location	User	Value	Reason
Aug-18-2020 01:26:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Closed	Response satisfies query
Aug-17-2020 20:02:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Unplanned Visit CFR has been updated
Aug-17-2020 01:34:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Reissued:Opened	PDQ: Requery: Thank you for response. As per section 8.43 of CRF Completion Requirements, please consider updating "Was contact made?" as 'Yes' and select the appropriate Contact Outcome option present on UNPLANNED VISIT (UNPL) form.
Aug-14-2020 15:50:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Please clarify page to address query
Aug-14-2020 07:51:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Reissued:Opened	PDQ: Requery: Thank you for confirming Subject was contacted via phone. As per section 8.43 of CRF Completion Requirements, please consider updating "Was contact made?" as 'Yes' and select the appropriate Contact Outcome option present on Form.

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Aug-13-2020 08:23:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Subject was contacted via phone. Symptoms resolved. No unplanned visit required.
Aug-12-2020 05:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Opened	PDQ: Subject has reported Severe symptoms/reaction in eDiary data on 07Aug2020. Please confirm if an UNPLANNED contact was made and update the data as appropriate
Aug-01-2020 16:52:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10851018	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-01-2020 16:52:13 (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-01-2020 16:53:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-01-2020 16:53:06 (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
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Aug-01-2020 16:53:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: WHITE	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-01-2020 16:53:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Aug/1/2020	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Inclusion Number: Criteria: Male or female participant between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (depende nt upon study stage) Criterion met?: Criterion ID: Criterion ID (For Pfizer use only):	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclu sive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at rando mization (dependent upon study sta	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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

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I.a Criterion met?

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> IN01A00	Initial Entry

I.b

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> 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?: Criterion ID: (For Pfizer use only): IN02A00	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

1.b Inclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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

1.b Criterion met?

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: IN02A00	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Inclusion Number:	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria on 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>Criteria met?: YES</p> <p>Criteria ID: IN03A00 (For Pfizer use only)</p>	
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:22***I.c Inclusion Number:***

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Inclusi 4 on Nu mber:	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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria Description: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol</p> <p>Criteria Met: YES</p> <p>Criteria ID: IN04A00 (For Pfizer use only)</p>	
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:22***1.d Inclusion Number:***

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exclus 1 ion Nu mber:	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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria on 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</p> <p>Criteria met?:</p> <p>Criteria ID: EX01A00 (For Pfizer use only)</p>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX01A00	Initial Entry
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2.b

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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: (Former Pfizer use only): EX02A00	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exclusion Number: 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)	Initial Entry

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Criteria NO on met ?: Criteria EX03A00 on ID: (For Pfizer use only):	
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2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX03A00	Initial Entry

2.d

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

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Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exclusion Number: 4 Criterion Description: Receipt of medications intended to prevent COVID-19 Criterion met?: NO Criterion ID: EX04A00 (For Pfizer use only):	Initial Entry

2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX04A00	Initial Entry

2.e

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

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Form Version: 30-Jul-2020 21:27

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Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exclusion Number: Criterion Description: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination Criterion met?: Criterion ID: EX08A00 (For Pfizer use only):	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

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Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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Subject Initials: ---

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2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Immunocompromised individuals with known or suspected immunod efficiency, as determined by history and/or laboratory/physical examina tion	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exclusi 10 on Nu mber:	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

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Form Version: 30-Jul-2020 21:27

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Subject No: 10851018

Generated By: pfe.levisse

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			<p>Criteria on Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p>Criteria met?: NO</p> <p>Criteria ID: EX10A00 (For Pfizer use only)</p>	
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:22**2.f Exclusion Number:**

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding Criterion met? NO :	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

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Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

			Criterion ID: (EX11A00 For Pfizer use only):	
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Women who are pregnant or breastf eeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exclusion Nu 12 mber: Criterion Des Previous vaccinati cription: on with any corona virus vaccine	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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			Criterion met NO ?: Criterion ID: EX12A00 (For Pfizer use only):	
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exclusion Number:	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX13A01	Initial Entry

2.j

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exclusion Number: Criterion Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study Criterion met?: Criterion ID: EX14A01 (For Pfizer use only):	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX14A01	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

2.k				
Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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Site Name: (1085) Ventavia Research Group

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Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exclusion Number: 17 Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Version: 30-Jul-2020 21:27

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Site No: 1085

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Generated Time (GMT): 29-Mar-2021 10:22

			Criterion NO met?: Criterion EX16A01 ID: (For Pfizer use only):	
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2.1 Exclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exclus 22 ion Nu	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 10:22

			<p>mber:</p> <p>Criterion Definition: 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>Criterion met?: NO</p> <p>Criterion ID: EX21A01</p> <p>Use only: (For Pfizer use only):</p>	
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

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Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

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Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 16:54:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EX21A01	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-01-2020 16:54:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Aug/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-01-2020 16:54:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-01-2020 16:56:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Left Ventricle Hypertrophy Start Date: May/UNK/2020 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:56:22 (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-01-2020 16:56:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Left Ventricle Hypertrophy	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 16:56:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: May/UNK/2020	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 16:56:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

I.b

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Aug-01-2020 16:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Te Hypertension rm: Start Date: UNK/UNK/2 015 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:56:53 (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-01-2020 16:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Hypertension	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 16:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: UNK/UNK/2015	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 16:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-01-2020 16:57:28 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

(US & Canada)			:	
			Medical History Term:	Seasonal Allergies
			Start Date:	UNK/UNK/2015
			Ongoing:	YES

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:57:28 (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-01-2020 16:57:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Seasonal Allergies	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 16:57:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: UNK/UNK/2015	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 16:57:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-01-2020 16:58:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Migraines	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			Start Date:	UNK/UNK/2000	
			Ongoing:	YES	

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:58:04 (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-01-2020 16:58:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Migraines	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 16:58:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: UNK/UNK/2000	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 16:58:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-01-2020 16:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Te Depression rm: Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.leivissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:58:42 (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 16:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Depression	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 16:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: UNK/UNK/2000	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 16:58:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-01-2020 16:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 6 r: Medical History Tubal Ligation Term: Start Date: UNK/UNK/200 5 Ongoing: NO End Date: UNK/UNK/ 2005	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.leivissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

If Line/MH Number:

Date	Location	User	Value	Reason
Aug-01-2020 16:59:21 (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-01-2020 16:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Tubal Ligation	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Aug-01-2020 16:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: UNK/UNK/2005	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
Aug-01-2020 16:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1085

Subject No: 10851018

Generated By: pfe.leviss

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-01-2020 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Aug/1/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-01-2020 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 230.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-01-2020 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-01-2020 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 67.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-01-2020 17:00:01 (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
Aug-01-2020 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 36.0	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1085

Subject No: 10851018

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

7.a

Date	Location	User	Value	Reason
Aug-01-2020 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Record Identifier:: 1 Temperature: 96.9 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-01-2020 17:00:01 (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
Aug-03-2020 05:45:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Closed	Query closed as per site response
Aug-01-2020 17:01:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Original value is correct
Aug-01-2020 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.9 F is outside of Normal Range 97 - 99.5 F.
Aug-01-2020 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 96.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-01-2020 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: F	Initial Entry

7.a Temperature Location:

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Aug-01-2020 17:00:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-01-2020 17:00:22 (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-01-2020 17:00:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-04-2021 13:25:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Monica McGuire (pfe.mcguim15)	Query 1: Closed	Response satisfies query
Mar-04-2021 12:35:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Subject was listed as having a tubal ligation and CRC mistakenly thought this made subject not a WOCBP. PD were previously noted
Mar-03-2021 10:58:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Monica McGuire (pfe.mcguim15)	Query 1: Opened	CLINQUERY- Please clarify why pregnancy tests were not performed. Subject is <60 yrs old and has no MH of surgical sterilization. Test is required for WOCBP. Please review and record PD, if applicable.

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.leivissc

Generated Time (GMT): 29-Mar-2021 10:22

Aug-01-2020 17:00:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Aug/1/2020	Initial Entry
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4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-01-2020 17:00:22 (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-01-2020 17:00:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-01-2020 17:00:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin in Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-01-2020 17:00:22 (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-01-2020 17:00:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

6.a Not Done:

Date	Location	User	Value	Reason
Aug-01-2020 17:00:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NOT DONE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-01-2020 17:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Aug/1/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-01-2020 17:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 41321	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-01-2020 17:01:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-01-2020 17:01:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-03-2020 14:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-01-2020 17:01:22 (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.
Aug-01-2020 17:01:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Date of Collection: Aug/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-03-2020 14:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BP5BT5	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

5.a Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> BP5BT5	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-03-2020 14:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Sample ID: BP5BT6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> BP5BT6	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-03-2020 14:18:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Sample ID: BP5BT7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:18:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> BP5BT7	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-03-2020 14:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Sample ID: BLD1V0	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

5.d Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:19:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BLD1V0	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-03-2020 14:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BLD1V1	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:19:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BLD1V1	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-01-2020 17:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-01-2020 17:01:35 (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-03-2020 14:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-01-2020 17:01:35 (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.
Aug-01-2020 17:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Date of Collection: Aug/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-03-2020 14:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BP5BSZ	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

5.a Sample ID

Date	Location	User	Value	Reason
Aug-03-2020 14:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BP5BSZ	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-01-2020 17:02:08 (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
Aug-01-2020 17:02:08 (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-01-2020 17:02:08 (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-01-2020 17:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Aug/1/2020 11:56	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-01-2020 17:02:08 (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-01-2020 17:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: LEFT	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851018

Generated By: pfe.leivissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

7. Route:

Date	Location	User	Value	Reason
Aug-01-2020 17:02:08 (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-01-2020 17:02:08 (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-01-2020 17:02:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-18-2020 19:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 1: Closed	Response satisfies query
Aug-17-2020 20:01:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Unplanned CRF has been updated.
Aug-16-2020 22:08:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 1: Opened	A contact outcome - unplanned CRF must be completed when a telephone contact or site visit occurs following suspected Grade 4 local reaction, systemic event or fever reported via e-diary. Refer to section 8.44. of CRF completion requirements for guidance
Aug-01-2020 17:02:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-22-2020 12:36:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Aug/22/2020	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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

[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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptom:: FE VE R Were fever or systemic symp NO toms present on the last day the Subject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptom:: FA TIG UE	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

			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
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:22**2.c Symptom:**

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptom:: CH IL LS Were fever or systemic sym NO ptoms present on the last da y the Subject Diary was com pleted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptom:: DIARRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing ? NO Stop Date: Au g/7/ 202 0	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

2.f Symptom:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Ongoing? NO Stop Date: Aug/7/2020	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptom:: NEW OR WORSEN ED MUS CLE PAI N Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was compl eted?:	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:22**2.g Symptom:**

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NEW OR WORSE NED JOINT 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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or systemi NO c symptoms present o n the last day the Subj ect Diary was complet ed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NEW OR WORSE NED JOINT PA IN	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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reaction s present on the last day the Subject Diary was complete d?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry
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5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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-22-2020 12:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Aug/22/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-22-2020 12:37:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Record Identifier:: 1 Temperature: 98.3 Temperature Unit: F Temperature Locat ion:: ORAL CAVI TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:50 (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
Aug-22-2020 12:37:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-22-2020 12:37:50 (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
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Aug-22-2020 12:37:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: ORAL CAVITY	Initial Entry
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-22-2020 12:38:04 (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
Aug-22-2020 12:38:04 (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
Aug-22-2020 12:38:04 (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
Aug-22-2020 12:38:04 (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
Aug-22-2020 12:38:04 (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
Aug-22-2020 12:38:04 (UTC-06:00) Central	ACV0PFEINFP6000	Banika Ervin	Data Entry: Sponsor-Defined Ide Not Applic	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Time (US & Canada)	(pfe.bervin)	ntifier:	able
		Test::	Not Applicable
		Result::	Not Applicable
		Not Done::	Not Applicable

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-22-2020 12:38:04 (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
Aug-22-2020 12:38:04 (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
Aug-22-2020 12:38:04 (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
Aug-22-2020 12:38:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-22-2020 12:38:18 (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 12:38:18 (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 12:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-22-2020 12:38:18 (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 12:38:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Date of Collection: Aug/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-22-2020 12:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BMD7R4	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

5.a Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 12:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BMD7R4	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-22-2020 12:38:41 (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
Aug-22-2020 12:38:41 (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-22-2020 12:38:41 (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-22-2020 12:38:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Aug/22/2020 11:21	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-22-2020 12:38:41 (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-22-2020 12:38:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: LEFT	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851018

Generated By: pfe.leivissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

7. Route:

Date	Location	User	Value	Reason
Aug-22-2020 12:38:41 (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-22-2020 12:38:41 (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-22-2020 12:38:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Nov-11-2020 23:57:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	31Oct2020 report was in error
Nov-11-2020 15:16:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Per subject 31Oct2020 report was in error
Nov-11-2020 00:49:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Reissued:Opened	RQ1: Thank you for response. However the symptoms start & end date on Covid illness form does not capture the Illness ed diary entry of 31OCT2020. Please review and update, else clarify.
Nov-10-2020 15:55:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Data added
Nov-10-2020 13:00:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 31Oct2020. But there is no COVID Illness visit reported in the database. Please clarify.
Sep-21-2020 11:45:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sep/21/2020	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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:22[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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Symptom:: FE VE R Were fever or systemic symp NO toms present on the last day the Subject Diary was compl eted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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: 1085 **Site Name:** (1085) Ventavia Research Group
Subject No: 10851018 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:22

			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
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:22**2.c Symptom:**

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Symptom:: CH IL LS Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
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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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?:	Initial Entry
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2.e Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?:	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:22**2.f Symptom:**

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Symptom:: NEW OR WORSE ED MUS CLE PAIN Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was comple ted?:	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

2.h

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Symptom:: NEW OR WORSE NED 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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NEW OR WORSE NED 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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: LEFT	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.leivissc

Generated Time (GMT): 29-Mar-2021 10:22

5.a

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reaction s present on the last day the Subject Diary was complete d?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction s present on the last day th e Subject Diary was compl eted?: NO	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:22**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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-21-2020 11:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 11:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 11:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-21-2020 11:45:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 11:45:22 (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.
Sep-21-2020 11:45:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 11:45:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BP9N66	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.leivissc

Generated Time (GMT): 29-Mar-2021 10:22

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 11:45:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> BP9N66	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-21-2020 11:45:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> Sample ID: BNVT8N	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 11:45:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> BNVT8N	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-21-2020 11:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> Sample ID: BNVT8P	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 11:45:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> BNVT8P	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 00:12:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 1: Closed	Per site confirmation_PD tracker updated
Mar-11-2021 08:50:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Query 1: Answered	Original value is correct
Mar-11-2021 02:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	PDQ: Date of visit at V4_MONTH6_L is out of window for 10 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. "[chandd38 SDQ=156142]"
Mar-09-2021 15:47:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Michael Johnson (pfe.mjohnson3)	Data Entry: Mar/9/20 21	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-09-2021 15:52:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-09-2021 15:52:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-10-2021 09:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-10-2021 06:00:35 (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.
Mar-09-2021 15:52:09 (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.
Mar-09-2021 15:52:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Michael Johnson (pfe mjohnson3)	Data Entry: YES Date of Collection: Mar/9/2021	Initial Entry

5.a

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Mar-10-2021 09:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BLD2GR	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 09:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BLD2GR	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-10-2021 09:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BLD2GS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 09:51:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BLD2GS	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-10-2021 09:51:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BR6WJX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 09:51:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BR6WJX	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/09/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Nov-12-2020 08:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Nov-12-2020 08:46:49 (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-11-2020 15:17:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-11-2020 01:19:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Opened	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-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-10-2020 15:56:03 (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-10-2020 15:56:03 (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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/09/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

				Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-10-2020 15:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Nov/9/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-10-2020 15:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Nov/9/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Nov/7/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Mar-09-2021 13:09:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Elizabeth Chatburn (pfe.chatbe)	Query 1: Closed	data updated
Mar-09-2021 10:19:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-09-2021 10:19:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO Date of Last Symptom Resolved: Nov/10/2020	Transcription Error
Feb-15-2021 07:39:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Selvabala Muthukrishnan (pfe.muthus32)	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.

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.leivissc

Generated Time (GMT): 29-Mar-2021 10:22

Nov-10-2020 15:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry
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4.a

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:22**4.b Symptoms:**

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.leivissc

Generated Time (GMT): 29-Mar-2021 10:22

Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom YES Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

4.f

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptoms NEW OR INCREASE : D SORE THROAT Symptom YES Present:	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Nov/09/2020**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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:22**4.g Symptoms:**

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NEW OR INCREASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 15:56:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-10-2020 15:57:06 (UTC-06:00) Central	ACV0PFEINFP6000	Banika Ervin	Data Entry: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Time (US & Canada)		(pfe.bervin)		
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7. Test Result:

Date	Location	User	Value	Reason
Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-10-2020 15:57:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-11-2020 15:17:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-11-2020 15:17:12 (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-13-2020 11:30:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Answer Auto Query
Nov-12-2020 14:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Carrie Nedrick (pfe.nedrickc)	Query 3: Reissued:Candidate	waiting for site update
Nov-12-2020 12:58:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 3: Answered	Swab obtained but not yet delivered to site. Will update once information received.
Nov-12-2020 09:59:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 3: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-12-2020 08:51:52 (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

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.leivissc**Generated Time (GMT):** 29-Mar-2021 10:22

				as appropriate.
Nov-12-2020 08:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-12-2020 08:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: YES Date of Collection: Nov/9/2020	Transcription Error
Nov-12-2020 08:46:49 (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.
Nov-12-2020 08:46:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-12-2020 08:46:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Transcription Error
Nov-11-2020 16:56:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-11-2020 15:17:12 (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.
Nov-11-2020 15:17:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Date of Collection:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Nov/11/2020	
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5.a

Date	Location	User	Value	Reason
Nov-13-2020 11:30:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sample ID: CV10949	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-13-2020 11:30:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: CV10949	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-10-2020 15:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-10-2020 15:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-12-2020 04:46:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Clo sed	Close per site response
Nov-11-2020 15:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Ans wered	Telehealth visit. Home nasal swab collected
Nov-11-2020 07:21:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW5346065;Sample Collected is not expected to be Not Done. Please review and update appropriately or clarify
Nov-10-2020 15:57:44 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not D one	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Canada)				
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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-10-2020 15:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/09/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 10:22***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

1.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 Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/09/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:22***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Type of Practitioner: OTH R Occurrence of Visits or C NO ontacts:	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 15:58:07 (UTC-06:00) Central	ACV0PFEINFP6000	Banika Ervin	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Time (US & Canada)		(pfe.bervin)		
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-10-2020 15:58:25 (UTC-06:00) Central	ACV0PFEINFP6000	Banika Ervin	Data Entry: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Time (US & Canada)		(pfe.bervin)		
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-10-2020 15:58:57 (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-10-2020 15:58:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-11-2020 21:00:57 (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_CEIDT008_03
Nov-11-2020 16:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Clo sed	Close Auto Query
Nov-11-2020 16:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry : 1	Transcription Error
Nov-11-2020 16:06:37 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Op ened	Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

Canada)				SOD CRF. Please review and update as appropriate.
Nov-11-2020 16:06:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Initial Entry
Nov-11-2020 16:06:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry : 0	Initial Entry
Nov-11-2020 16:06:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry :	Initial Entry
Nov-11-2020 16:00:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Rei ssued: Open ed	DM: Please note that the Toxicity Grade should be a numeric value between 0 - 5.
Nov-11-2020 11:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Query 1: An swere d	Changed data per query
Nov-11-2020 02:55:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW5346076;Toxicity Grade is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Nov-10-2020	ACV0PFEINFP6000	Banika Ervin	Data	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

15:58:45 (UTC-06:00) Central Time (US & Canada)		(pfe.bervin)	Entry : Not D one	
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Nov-10-2020 15:59:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Lab Normal Range:	Not Done
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45	ACV0PFEINFP6000	Banika	Data Entry:	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

(UTC-06:00) Central Time (US & Canada)		Ervin (pfe.bervin)	Sponsor-Defined Identifier:	Not Done	
			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.leivissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.leivissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Test::	Not Done	
				e	
			Result::	Not Done	
				e	
			Not Done::	Not Done	
				e	
			Lab Normal Range:	Not Done	
				e	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.leivissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.leivissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Test::	Not Done
			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**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:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.leivissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Test::	Not Done
				e
			Result::	Not Done
				e
			Not Done::	Not Done
				e
			Lab Normal Range:	Not Done
				e

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.leivissc

Generated Time (GMT): 29-Mar-2021 10:22

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-10-2020 15:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Lab Normal Range:	Not Done
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	<u>Data Entry:</u> Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39	ACV0PFEINFP6000	Banika	<u>Data Entry:</u>	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

(UTC-06:00) Central Time (US & Canada)		Ervin (pfe.bervin)	Sponsor-Defined Identifier:	Not Done	
			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.leivissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Test::	Not Done
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			Result::	Not Done
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			Not Done::	Not Done
				e
			Lab Normal Range:	Not Done
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.leivissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

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Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

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Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Test::	Not Done
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			Result::	Not Done
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			Not Done::	Not Done
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			Lab Normal Range:	Not Done
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

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Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Test::	Not Done
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			Result::	Not Done
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			Not Done::	Not Done
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			Lab Normal Range:	Not Done
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.leivissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Test::	Not Done
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			Result::	Not Done
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			Not Done::	Not Done
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			Lab Normal Range:	Not Done
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.leivissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

			Test::	Not Done
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			Result::	Not Done
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			Lab Normal Range:	Not Done
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.leivissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

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			Result::	Not Done
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			Not Done::	Not Done
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			Lab Normal Range:	Not Done
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851018**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:22**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

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Generated Time (GMT): 29-Mar-2021 10:22

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			Result::	Not Done
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			Not Done::	Not Done
				e
			Lab Normal Range:	Not Done
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

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Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.i Result:

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Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

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Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sponsor-Defined Identifier: Not Done	Initial Entry

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Header Text: c4591001

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			Test::	Not Done
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			Result::	Not Done
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			Not Done::	Not Done
				e
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Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-10-2020 16:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-10-2020 16:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Record Identifier:: Not D one Systolic:: Not D one Diastolic:: Not D one Respiratory Rate in respi rations/minute: Not D one Heart Rate in beats/minu te: Not D one	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
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Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

Nov-10-2020 16:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry
---	-----------------	---------------------------------	--------------------------------	---------------

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Date:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-10-2020 16:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Record Identifier:: Not Done Oxygen Saturation: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-10-2020 16:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date Time of Assessment:

Date	Location	User	Value	Reason
Nov-10-2020 16:01:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Nov-10-2020 16:01:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Nov-10-2020 16:01:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-10-2020 16:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-10-2020 16:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-10-2020 16:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	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
Nov-10-2020 16:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-10-2020 16:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

6. Ongoing?

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Nov-10-2020 16:02:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-10-2020 16:02:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Nov-10-2020 16:02:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Nov-10-2020 16:02:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Nov-10-2020 16:02:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Done	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/08/2020

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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-08-2020 10:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Dec/8/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-08-2020 10:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: COVID_A1	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Dec/08/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.lewissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-08-2020 10:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-08-2020 10:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-08-2020 10:24:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 10:23:44 (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.
Dec-08-2020 10:23:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: YES Date of Collection: Dec/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-08-2020 10:24:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sample ID: BNZL2F	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/08/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.leivissc

Generated Time (GMT): 29-Mar-2021 10:22

5.a Sample ID

Date	Location	User	Value	Reason
Dec-08-2020 10:24:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	<u>Data Entry:</u> BNZL2F	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-08-2020 10:24:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	<u>Data Entry:</u> Sample ID: BS7WBP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-08-2020 10:24:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	<u>Data Entry:</u> BS7WBP	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-08-2020 10:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	<u>Data Entry:</u> Sample ID: BS7WBR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-08-2020 10:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	<u>Data Entry:</u> BS7WBR	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/08/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-17-2020 19:59:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Aug/8/2020	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/08/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

I. Assessments

Date	Location	User	Value	Reason
Aug-17-2020 20:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 20:00:02 (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-17-2020 20:00:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/08/2020

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Aug-17-2020 20:01:08 (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
Aug-17-2020 20:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Date of Contact: Aug/8/2020 Contact Outcome: VISIT NOT ARRANGED, RE ACTION NO LONGER PRESE NT	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Aug-17-2020 20:01:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Reaction resolved the afternoon of 08Aug2020 per subject.	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-22-2020 12:13:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sep/21/2020	Transcription Error
Sep-21-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Aug/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-21-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-21-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (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, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851018

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 15:03:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Jan/11/2021	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1085**Subject No:** 10851018**Generated By:** pfe.levissc**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History**Form Status:** Data Complete, Frozen**Site Name:** (1085) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**I. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Mar-12-2021 00:41:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloi (pfe.moloim)	Query 1: Closed	Response satisfies query
Mar-11-2021 15:04:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Query 1: Answered	Changed data per query
Mar-10-2021 15:49:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Laurie Hawes (pfe.hawesl01)	Query 1: Opened	FURTHER VACCINATION CONFIRMATION form is completed, yet DATE OF VISIT form is not completed. Please review and update as appropriate.
Mar-01-2021 15:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible and NOT confirmed to have received only placeb o at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-01-2021 15:17:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Jan/11/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-01-2021 15:17:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Mar-01-2021 15:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.levissc

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Mar-03-2021 21:00:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Christian Mayfield (pfe.mayfic01)	Query 1: Clos ed	Response satisfies query
Mar-03-2021 11:30:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Query 1: Ans wered	Please unfreeze so query can be updated
Mar-03-2021 08:16:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW7565369;Date of Collection/Notification of Death is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Mar-01-2021 15:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Not A pplica ble	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851018

Generated By: pfe.lewissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Sep-21-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-01-2020 17:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-01-2020 16:54:29 (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 09:10:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - SAE (#2021264511) received for Endometriosis / Endometrial Thickening; however, no entry on the AE log CRF is present. Please report this AE on the AE CRF.
Sep-22-2020 12:13:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/21/2020	Transcription Error
Sep-21-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/22/2020	Initial Entry
Aug-01-2020 17:00:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/1/2020	Initial Entry
Aug-01-2020 16:54:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/1/2020	Initial Entry

090177e196ae3d8e\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851018

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

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