

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1085

Subject No: 10851129

Generated By: pfe.levisse

Form: COHORT SELECTION

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](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/18/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10851129]
2.	Birth Date:	(b) (6)/1985
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

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/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1085

Subject No: 10851129

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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/18/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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

[Form Comments](#)

Medical History Details

1.	Line/MH Number:	Not Applicable _____ []
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1085

Subject No: 10851129

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/18/2020
2.	Weight:	[155.3]
3.	Unit:	LB
4.	Height:	[70.1]
5.	Unit:	in
6.	Body Mass Index:	[22.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1085

Subject No: 10851129

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/18/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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/18/2020
2.	Randomization Number:	[55274]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BMD7NT]
5.b	Sample ID	[BMD7NV]
5.c	Sample ID	[BMD7NW]
5.d	Sample ID	[BLD1ZM]
5.e	Sample ID	[BLD1ZN]

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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/18/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BMD7NS]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851129

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/18/2020 17:19
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

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1085

Subject No: 10851129

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	NO - REACTOGENICITY E-DIARY NOT 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: 10851129

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/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1085

Subject No: 10851129

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:	Sep/10/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.2]
	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: 10851129

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/10/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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: Sep/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5BN4]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851129

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:	Sep/10/2020 17:06
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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	Oct/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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: Oct/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9NGH]
5.b	Sample ID	[BNVTGZ]
5.c	Sample ID	[BNVTH0]

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

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: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

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: 10851129

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

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

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: 10851129

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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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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/13/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
----	-------------------------	---------

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Jan/13/2021

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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:	Jan/13/2021
2.	Date of First Symptom Started:	Jan/12/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/13/2021

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?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Jan/13/2021

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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: 10851129

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 Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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: Jan/13/2021
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	[RW90153]
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090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[home swab performed]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Jan/13/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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
----	--	----

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

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: 10851129

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 Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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[eCRF Audit Trail History](#)

Respiratory Treatment

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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: 10851129

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 Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE

Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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[eCRF Audit Trail History](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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 Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/13/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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[eCRF Audit Trail History](#)

Lab Chemistry Details

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Jan/13/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

5 f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

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 Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Jan/13/2021

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Laboratory Data Hematology

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
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Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

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5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
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Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

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5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
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Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

5 f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
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Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

5.h	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.i	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
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Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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

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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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Jan/13/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Vital Signs

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

Vital Signs Details

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

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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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Jan/13/2021

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Vital Signs

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

Vital Signs Details

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

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

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 Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS

Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	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: 10851129

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 Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Jan/13/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	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 Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

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 Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.lewissc

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

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/10/2021

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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/10/2021

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: 10851129

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: Feb/10/2021
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	[BR6WC9]
5.b	Sample ID	[BLD2C7]
5.c	Sample ID	[BLD2C8]

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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 - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1085

Subject No: 10851129

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 :	Oct/8/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1085

Subject No: 10851129

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

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](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Feb/24/2021
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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: 10851129

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: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levisse

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Exposure During Pregnancy	Dec/23/2020 UNK: UNK	YES	Repeating Pages

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure During Pregnancy]	
4.	Start Date Time:	Dec/23/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unknown]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	NO	
12.	Was a Non-Drug Treatment given?	NO	

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

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: 10851129

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR

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](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Medication Error

1.	Category:	Not Applicable _____	Comments
2.	Medication Error (Type of Medication Error):	Not Applicable _____ []	Comments
3.	Start Date:	Not Applicable _____ //	Comments
4.	Is the medication error still ongoing?	Not Applicable _____	Comments
5.	Latest Action Taken with Study Treatment:	Not Applicable _____	Comments
6.	Was a Concomitant Medication given?	Not Applicable _____	Comments
7.	Was a Non-Drug Treatment given?	Not Applicable _____	Comments
8.	Did the Medication Error cause the subject to be discontinued from the study?	Not Applicable _____	Comments
9.	Was this medication error associated with any adverse events?	Not Applicable _____	Comments
10.	Serious Adverse Event Number: For Pfizer Use Only	Not Applicable _____ []	Comments

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

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: 10851129

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:	//

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

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: 10851129

Generated By: pfe.levissc

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?	

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

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: 10851129

Generated By: pfe.levissc

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?	

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: 10851129

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: 10851129

Generated By: pfe.levissc

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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: 10851129

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: 10851129

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:	

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: 10851129

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?	

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

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: 10851129

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: 10851129

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: 10851129

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: 10851129

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: 10851129

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: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/16/2021
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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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 per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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/16/2021
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: 10851129

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT

Form Status: Incomplete, Queries, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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 _____ []

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

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: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Informed Consent - Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	
----	---	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

Generated By: pfe.levisse

Form: SUBJECT STATUS

Form Status: Data Complete, 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	DISCONTINUED
2.	Subject Status Date	Feb/24/2021

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: 10851129

Subject Initials: ---

Generated By: pfe.levisse

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: 10851129

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: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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Item	Date	User	Comment
Form	Aug-19-2020 09:52:14 (UTC-06:00) Central Time (US & Canada)	Angi Cox (pfe.acox1)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Aug-19-2020 09:55:47 (UTC-06:00) Central Time (US & Canada)	Angi Cox (pfe.acox1)	Not Applicable

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
Form	Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
1	Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
2	Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

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Item	Date	User	Comment
3	Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

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Subject Initials: ---

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Item	Date	User	Comment
4	Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen

Site No: 1085

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Subject No: 10851129

Subject Initials: ---

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Item	Date	User	Comment
5	Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1085

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Subject No: 10851129

Subject Initials: ---

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Item	Date	User	Comment
6	Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1085

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Subject No: 10851129

Subject Initials: ---

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Item	Date	User	Comment
7	Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

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Item	Date	User	Comment
8	Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

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Item	Date	User	Comment
9	Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
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Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
Form	Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
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Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

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Item	Date	User	Comment
1	Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
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Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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Item	Date	User	Comment
2	Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
3	Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
4	Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments
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Item	Date	User	Comment
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Item	Date	User	Comment
6	Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments
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Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

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Item	Date	User	Comment
Form	Jan-13-2021 15:41:00 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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Item	Date	User	Comment
1	Jan-13-2021 15:41:00 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Jan/13/2021

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Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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Item	Date	User	Comment
2	Jan-13-2021 15:41:00 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments
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Item	Date	User	Comment
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Site Name: (1085) Ventavia Research Group

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Item	Date	User	Comment
4	Jan-13-2021 15:41:00 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen

Site No: 1085

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Item	Date	User	Comment
Form	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Site No: 1085

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Item	Date	User	Comment
1	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
4	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1085

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Subject Initials: ---

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Item	Date	User	Comment
5.a	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

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Item	Date	User	Comment
5.a	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
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Form Status: Data Complete, Frozen

Site No: 1085

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Item	Date	User	Comment
5.a	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.a	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
5.b	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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Item	Date	User	Comment
5.b	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

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Item	Date	User	Comment
5.b	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
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Item	Date	User	Comment
5.b	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

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Item	Date	User	Comment
5.c	Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1085

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Subject No: 10851129

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5.e	Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
4	Jan-13-2021 15:42:57 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Jan/13/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
5	Jan-13-2021 15:42:57 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments
Jan/13/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
6	Jan-13-2021 15:42:57 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
Form	Jan-13-2021 15:43:14 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
1	Jan-13-2021 15:43:14 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
2	Jan-13-2021 15:43:14 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
3	Jan-13-2021 15:43:14 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
4	Jan-13-2021 15:43:14 (UTC-06:00) Central Time (US & Canada)	Claudia Alonzo (pfe.calonzo)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Queries

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
6	Mar-03-2021 14:27:32 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
1	Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
2	Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
3	Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
4	Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
5	Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
6	Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
7	Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
8	Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
9	Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
10	Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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

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Item	Date	User	Comment
Form	Mar-03-2021 13:25:16 (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: 10851129

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

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Item	Date	User	Comment
1	Mar-03-2021 13:25:16 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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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
Banika Ervin	N/A	Feb-10-2021 12:35:20 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Gregory Fuller	Approved	Jan-21-2021 13:10:08 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

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	Jan-13-2021 15:35:38 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Gregory Fuller	Approved	Oct-22-2020 13:13:22 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

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.

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1085

Subject No: 10851129

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-19-2020 09:51:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 09:51:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	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: 10851129

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

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-19-2020 09:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: OBTAINED Date Written Consent Obtained Aug/18/2020	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-19-2020 09:51:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10851129	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-19-2020 09:51:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1985	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-19-2020 09:52:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-19-2020 09:52:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 09:52:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: WHITE	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

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

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-19-2020 09:52:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Aug/18/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-19-2020 09:52:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Aug/18/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-19-2020 09:52:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-19-2020 09:52:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1085

Subject No: 10851129

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

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1. Date:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Aug/18/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: 155.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: 70.1	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22.2	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1085

Subject No: 10851129

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

7.a

Date	Location	User	Value	Reason
Aug-19-2020 09:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Record Identifier:: 1 Temperature: 98.5 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: 98.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Aug/18/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-19-2020 09:56:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-19-2020 09:56:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

			Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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-19-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Aug/18/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-19-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: 55274	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 09:53:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 09:53:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-19-2020 09:53:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 09:53:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 09:53:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 09:53:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BMD7NT	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

Aug-19-2020 09:53:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BMD7NT	Initial Entry
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5.b

Date	Location	User	Value	Reason
Aug-19-2020 09:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BMD7NV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 09:54:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BMD7NV	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-19-2020 09:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BMD7NW	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 09:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BMD7NW	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-19-2020 09:54:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BLD1ZM	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 09:54:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BLD1ZM	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-19-2020 09:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BLD1ZN	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 09:55:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BLD1ZN	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 09:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 09:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-19-2020 09:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 09:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 09:52:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES Date of Collection: Aug/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 09:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BMD7NS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

Aug-19-2020 09:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BMD7NS	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851129

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-19-2020 09:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-19-2020 09:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-19-2020 09:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-19-2020 09:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Aug/18/2020 17:19	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-19-2020 09:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-19-2020 09:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: LEFT	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851129

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

7. Route:

Date	Location	User	Value	Reason
Aug-19-2020 09:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-19-2020 09:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 09:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1085

Subject No: 10851129

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](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-19-2020 09:57:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-12-2020 10:53:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Sep/10/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1085

Subject No: 10851129

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

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1. Date:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Sep/10/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-12-2020 10:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Record Identifier:: 1 Temperature: 97.2 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 97.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1085

Subject No: 10851129

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

Sep-12-2020 10:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Sep/10/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-12-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-12-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier 113	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

			Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

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
Sep-12-2020 13:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-12-2020 13:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-12-2020 13:52:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-12-2020 13:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-12-2020 13:51:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Date of Collection: Sep/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-12-2020 13:52:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BP5BN4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-12-2020 13:52:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BP5BN4	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851129

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-12-2020 10:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-12-2020 10:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Sep/10/2020 17:06	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: LEFT	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851129

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

7. Route:

Date	Location	User	Value	Reason
Sep-12-2020 10:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-12-2020 10:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-12-2020 10:54:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 14:51:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Oct/8/2020	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-08-2020 14:52:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-08-2020 14:52:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-08-2020 14:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 14:52:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 14:52:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-08-2020 14:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BP9NGH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

Oct-08-2020 14:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BP9NGH	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-08-2020 14:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BNVTGZ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 14:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BNVTGZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 14:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BNVTH0	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 14:52:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BNVTH0	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-13-2021 15:38:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-13-2021 15:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-13-2021 15:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-13-2021 15:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Jan/13/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-13-2021 15:35:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Jan/13/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Jan/12/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO Date of Last Symptom Resolved: Jan/13/2021	Initial Entry

4.a

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57	ACV0PFEINFP6000	Claudia	Data Entry:	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Jan/13/2021 Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-06:00) Central Time (US & Canada)		Alonzo (pfe.calonzo)	NO	
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4.b

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NEW OR INCREASED SHORTNE SS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom NO Present:	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NEW OR INCREASED MUSCLE P AIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Symptoms: NEW LOSS OF TAST E OR SMELL Symptom P NO resent:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NEW LOSS OF TASTE OR SMEL L	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Symptoms NEW OR INCREASE : D SORE THROAT	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Jan/13/2021 Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.lewissc

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

			Symptom NO Present:	
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4.g Symptoms:

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	<u>Data Entry:</u> NEW OR INCREASED SORE THR OAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	<u>Data Entry:</u> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	<u>Data Entry:</u> Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	<u>Data Entry:</u> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time	ACV0PFEINFP6000	Claudia Alonzo	<u>Data Entry:</u> Symptoms: VOMITING	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

(US & Canada)		(pfe.calonzo)	Symptom Present: NO	
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4.i Symptoms:

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-13-2021 15:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

7. Test Result:

Date	Location	User	Value	Reason
Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-13-2021 15:38:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-13-2021 15:38:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-13-2021 15:38:33 (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
Jan-13-2021 15:38:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 15:38:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-13-2021 15:38:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: YES Date of Collection: Jan/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-13-2021 15:38:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sample ID: RW90153	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/13/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

Jan-13-2021 15:38:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: RW90153	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-13-2021 15:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-13-2021 15:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-13-2021 15:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: home swab performed	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/13/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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I.a

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Type of Practitioner: EMERGENC Y ROOM Occurrence of Visit s or Contacts: NO	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/13/2021**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851129**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:22***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
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Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

			Occurrence of Visits or NO r Contacts:	
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Type of Practitioner: TELEPHONE C ONSULTATION Occurrence of Vi NO sits or Contacts:	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
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090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Jan/13/2021

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 15:39:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: RESPIRATORY TREATMENT - eCRF Audit Trail History
Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-13-2021 15:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-13-2021 15:40:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jan-13-2021 15:40:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-13-2021 15:40:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: 1	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History
Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-13-2021 15:41:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

			Lab Normal Range: Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

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Subject Initials: ---

Generated By: pfe.levissc

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

			Test::	Not Applicable
			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Subject Initials: ---

Generated By: pfe.levissc

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5.c

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

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Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levisse

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

			Result:: Not Applicable	
			Not Done:: Not Applicable	
			Lab Normal Range: Not Applicable	

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.e

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

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Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

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5.f

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

			Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Subject Initials: ---

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Subject Initials: ---

Generated By: pfe.levissc

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

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Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

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			Lab Normal Range: Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
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Site No: 1085

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Subject No: 10851129

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

			Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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5.b Not Done:

Date	Location	User	Value	Reason
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5.c

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable	Initial Entry

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5.h Test:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.i

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
Jan/13/2021 Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

			Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-13-2021 15:41:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/13/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Date:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-13-2021 15:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Record Identifier:: Not Appl icable Systolic:: Not Appl icable Diastolic:: Not Appl icable Respiratory Rate in res Not Appl pirations/minute: icable Heart Rate in beats/min Not Appl ute: icable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:09 (UTC-06:00) Central Time	ACV0PFEINFP6000	Claudia Alonzo	Data Entry: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
Jan/13/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

(US & Canada)

(pfe.calonzo)

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Jan/13/2021

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Date:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-13-2021 15:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Record Identifier:: Not Applicabl e Oxygen Saturation Not Applicabl : e	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-13-2021 15:42:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History
Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Jan-13-2021 15:42:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-13-2021 15:42:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Jan/13/2021 Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-13-2021 15:42:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	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
Jan-13-2021 15:42:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-13-2021 15:42:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

Jan-13-2021 15:42:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History
Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-13-2021 15:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-13-2021 15:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-13-2021 15:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-13-2021 15:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/10/2021

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851129

Generated By: pfe.lewissc

Form: DATE OF VISIT - ILLNESS CONVALESCENT - 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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 12:35:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Feb/10/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-10-2021 12:35:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/10/2021

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-10-2021 12:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-10-2021 12:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-10-2021 12:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 12:35:35 (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.
Feb-10-2021 12:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Date of Collection: Feb/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-10-2021 12:40:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BR6WC9	Transcription Error
Feb-10-2021 12:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: .BR6WC9	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/10/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 12:40:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-10-2021 12:40:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BR6WC9	Transcription Error
Feb-10-2021 12:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Feb-10-2021 12:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: .BR6WC9	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-10-2021 12:41:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BLD2C7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 12:41:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BLD2C7	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-10-2021 12:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Sample ID: BLD2C8	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/10/2021

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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

5.c Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 12:41:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: BLD2C8	Initial Entry

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 15-Sep-2020 21:55**Site No:** 1085**Subject No:** 10851129**Generated By:** pfe.levisse**Form:** DISPOSITION - TREATMENT - 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
Oct-15-2020 02:02:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe mahadp07)	Query 1: Closed	Closed as data updated.
Oct-14-2020 07:15:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-14-2020 07:15:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Oct/8/2020	Transcription Error
Oct-14-2020 00:09:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ankita Thakur (pfe.thakua20)	Query 1: Reissued:Opened	DM1: Thank you for the response, now the EOT form is unfrozen , hence please update the data appropriate as per the below query. Else clarify.
Oct-13-2020 16:32:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alicia Cruz (pfe.acruz)	Query 1: Answered	Can you please unfreeze this page
Oct-13-2020 06:06:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rajashekhhar Reddy (pfe reddyr51)	Query 1: Opened	DM: As per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please update date of EOT to match the date the Visit 3(1 month) visit was completed.
Sep-21-2020 14:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sep/10/2020	Initial Entry

2. Phase of Disposition:

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: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Sep-21-2020 14:56:03 (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 14:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1085

Subject No: 10851129

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP - 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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-09-2021 14:09:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Feb/24/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-09-2021 14:09:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-09-2021 14:09:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: ADVERSE EVENT	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851129

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Form Created	

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Category:

Date	Location	User	Value	Reason
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-25-2021 12:18:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	moving query location
Feb-25-2021 12:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL As per CRF CG 8.50.2.5, a healthy pregnancy is not an AE term; instead "Exposure During Pregnancy" will be recorded as an AE in the CRF until 6 months after the last dose of study intervention
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-05-2021 10:51:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Mar-04-2021 12:27:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Mar-04-2021 12:27:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Mar-04-2021 12:26:58	ACV0PFEINFP6000	Kathryn	Query 3: Reissued:Opened	Clinical - thank you;

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Header Text: c4591001 Visit: Logs - Unscheduled Form Version: 22-Apr-2020 21:02 Site No: 1085 Subject No: 10851129 Generated By: pfe.levissc				
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History Form Status: Data Complete, Queries Site Name: (1085) Ventavia Research Group Subject Initials: --- Generated Time (GMT): 29-Mar-2021 10:22				
(UTC-06:00) Central Time (US & Canada)		Sewell (pfe.sewelk02)		however contraception method was not in most recent PG safety update (01Mar21)
Mar-03-2021 14:22:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Data has been corrected
Mar-03-2021 14:22:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Data has been corrected
Mar-03-2021 14:22:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Data has been corrected
Mar-03-2021 14:22:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exposure During Pregnancy	Data has been corrected
Feb-25-2021 12:23:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical Please submit a PG safety update reporting contraception method in trial, and stop date if pertinent
Feb-25-2021 12:19:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Please submit a PG safety update with remaining subject demographics (Bday, race, ethnicity); also report Investigator Awareness date
Feb-25-2021 12:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL As per CRF CG 8.50.2.5, a healthy pregnancy is not an AE term; instead "Exposure During Pregnancy" will be recorded as an AE in the CRF until 6 months after the last dose of study intervention
Feb-24-2021 13:34:53	ACV0PFEINFP6000	Banika Ervin	Data Entry:	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.levisss

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

(UTC-06:00) Central Time (US & Canada)		(pfe.bervin)	Pregnancy	
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4. Start Date Time:

Date	Location	User	Value	Reason
Mar-11-2021 20:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical - thank you for clarifying. Please submit a PG safety report update stating Estimated date of Conception (23Dec20) is based on OB ultrasound in first trimester (w/ date of US).
Mar-11-2021 17:08:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Query 1: Answered	This date is based off the ultrasound not the cycle.
Mar-11-2021 11:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical - SAE update has start date of 23Dec2020 (not the same as AE start date); this is 4 days after 1st day of LMP (19Dec2020). Please clarify this date - it does not match reported Estimated Date of Conception = 02Jan2021
Mar-11-2021 09:48:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Dec/23/2020 UNK:UNK	Transcription Error
Mar-11-2021 09:48:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Jan/2/2021 UNK:UNK	Transcription Error
Mar-11-2021 09:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-11-2021 09:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Dec/23/2020 UNK:UNK	Transcription Error

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090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1085
Subject No: 10851129
Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
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Mar-11-2021 09:39:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical - SAE update has start date of 23Dec2020 (not the same as AE start date); this is 4 days after 1st day of LMP (19Dec2020). Please clarify this date - it does not match reported Estimated Date of Conception = 02Jan2021
Mar-10-2021 08:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Query 1: Answered	Will send updated form.
Mar-09-2021 21:22:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical thank you; please submit this updated Start date to the PG safety report
Mar-09-2021 14:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-09-2021 14:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Jan/UNK/2021 UNK:UNK	Transcription Error
Mar-05-2021 10:50:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical thank you; please submit this updated Start date to the PG safety report
Mar-04-2021 12:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-04-2021 12:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Jan/2/2021 UNK:UNK	Changed Information
Mar-04-2021 12:26:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical - PG Start date is UNK Jan 2021; however, PG Safety report gives date of estimated conception as 02 Jan 2021. Please review, harmonize reporting,

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1085**Subject No:** 10851129**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Queries**Site Name:** (1085) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

				and update where applicable
Mar-03-2021 14:27:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-03-2021 14:27:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Jan/UNK/2021 UNK:UNK	Transcription Error
Feb-26-2021 12:39:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - PG Start date is UNK Feb 2021; however, PG Safety report start date is 02 Jan 2021 (date of estimated conception). Please review, harmonize reporting, and update where applicable
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Feb/UNK/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-10-2021 03:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Malerato Mloi (pfe.moloim)	Query 1: Closed	Response satisfies query
Mar-09-2021 14:10:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Query 1: Answered	Changed data per query
Mar-09-2021 14:09:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

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Date	Location	User	Value	Reason
Mar-04-2021 12:25:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Mar-03-2021 14:27:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry
Mar-03-2021 14:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Entry error
Mar-03-2021 14:27:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry:	Entry error
Feb-25-2021 12:16:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL As per CRF CG 8.50.2.5, the toxicity grade for "Exposure During Pregnancy" is reported as Not Applicable
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.****Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-04-2021 01:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query

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Header Text: c4591001

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Generated By: pfe.levissc

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Form Status: Data Complete, Queries

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-03-2021 14:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-03-2021 14:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NOT APPLICABLE	Transcription Error
Feb-26-2021 04:28:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2021150192 ,action taken was reported as WITHDRAWN in AE CRF while NOT APPLICABLE in Safety database.Please confirm. If safety update is required, please submit a follow up form
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: DRUG WITHDRAWN	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-10-2021 03:30:31 (UTC-06:00) Central	ACV0PFEINFP6000	Malerato Moloi	Query 1: Closed	Response satisfies query

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Queries**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851129**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 10:22

Time (US & Canada)		(pfe.moloim)		
Mar-09-2021 14:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Mar-09-2021 14:07:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NOT RECOVERED/NOT RESOL VED	Transcription Error
Mar-04-2021 08:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe.margap03)	Query 1: Reissued:Opened	Response does not satisfy query
Mar-03-2021 14:22:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Term has been corrected
Mar-03-2021 14:22:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Exposure During Pregnancy : Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: UNKNOWN	Initial Entry

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

Date	Location	User	Value	Reason
Mar-09-2021 15:55:34 (UTC-06:00) Central Time	ACV0PFEINFP6000	Hayley Wyper	Query 1: Closed	Response satisfies query

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(US & Canada)		(pfe.wyperh)		
Mar-09-2021 14:10:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Query 1: Answered	Changed data per query
Mar-03-2021 07:11:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Entry indicates subject discontinued participation in study due to this event. If correct, please update the FUP tab to indicate end of study
Feb-24-2021 13:34:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - 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

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1. Category:

Date	Location	User	Value	Reason
Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

2. Medication Error (Type of Medication Error):

Date	Location	User	Value	Reason
Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

3. Start Date:

Date	Location	User	Value	Reason
Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

4. Is the medication error still ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

5. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

6. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

8. Did the Medication Error cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

9. Was this medication error associated with any adverse events?

Date	Location	User	Value	Reason
Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

10. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-24-2021 13:35:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851129

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 13:26:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Jan/16/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1085

Subject No: 10851129

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

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

Date	Location	User	Value	Reason
Mar-03-2021 13:27:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Participant is willing to return for Va ccination 3 Participant is: eligible per other protocol allowa nce(s) and confirmed to have rec eived only placebo at Vaccinatio n 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-03-2021 13:25:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Jan/16/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-03-2021 13:25:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: ASSESS ELIGIBILITY FOR ADDI TIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Incomplete, Queries, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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I. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Mar-12-2021 02:46:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 2: Op ened	DM: If there is no data needs to be reported on this page, kindly consider marking form as Not Applicable by selecting form level comment or else update the details. Thank you.
Mar-11-2021 21:08:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_20
Mar-11-2021 15:45:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Mar-11-2021 15:45:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry :	Transcription Error
Mar-10-2021 13:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (pfe.rosenr16)	Query 1: Rei ssued: Opene d	DM: Forms have been unfrozen. Please update the data per prior query. Thank you.
Mar-10-2021 08:21:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Query 1: Ans wered	Please make sure pages are unlocked before you enter something as a query. This takes more time when this is not done.

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Incomplete, Queries, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Mar-09-2021 22:35:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7650737; 'Withdrawal of Consent Date' is after 'Date of Completion/Discontinuation '/Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Mar-03-2021 13:26:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry : Mar/1 /2021	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

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

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I. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Mar-03-2021 13:25:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1085**Subject No:** 10851129**Generated By:** pfe.levisse**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1085) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**I. Subject Status**

Date	Location	User	Value	Reason
Mar-09-2021 14:09:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Sep-21-2020 14:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-19-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-19-2020 09:52:24 (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-09-2021 14:09:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Feb/24/2021	Initial Entry
Feb-25-2021 12:14:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-15-2021 09:37:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical A safety event of Pregnancy was submitted (PG safety report #2021150192); however, the event has not been entered on the AE CRF. Please report PG on AE CRF.
Oct-14-2020 07:15:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/8/2020	Transcription Error
Sep-21-2020 14:56:03 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/10/2020	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851129

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Time (US & Canada)				
Aug-19-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/18/2020	Initial Entry
Aug-19-2020 09:52:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/18/2020	Initial Entry

090177e196ae3d90\Final\Final On: 01-Apr-2021 04:38 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851129

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 11:28:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alicia Cruz (pfe.acruz)	Data Entry: Click Here to Enable	Initial Entry