

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

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 Sep/2/2020
----	--------------	---

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: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10851246]
2.	Birth Date:	(b) (6)/1987
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

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/2/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1085

Subject No: 10851246

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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 _____
----	--	-------------------------

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851246

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851246

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 _____

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1085

Subject No: 10851246

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:	Sep/2/2020
2.	Weight:	[247.0]
3.	Unit:	LB
4.	Height:	[67.0]
5.	Unit:	in
6.	Body Mass Index:	[38.7]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1085

Subject No: 10851246

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/2/2020
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:	

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851246

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 :	Sep/2/2020
2.	Randomization Number:	[78304]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5BLN]
5.b	Sample ID	[BNVT60]
5.c	Sample ID	[BNVT61]

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

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?	YES Date of Collection: Sep/2/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5BJ6]
-----	-----------	----------

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851246

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/2/2020 14:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1085

Subject No: 10851246

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
----	---	---

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

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	Sep/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/25/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1085

Subject No: 10851246

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/25/2020
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:	

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

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?	YES Date of Collection: Sep/25/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9N88]
-----	-----------	----------

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

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/25/2020 12:04
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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (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: 10851246 **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/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1085 **Site Name:** (1085) Ventavia Research Group

Subject No: 10851246 **Subject Initials:** ---

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNZKP3]
5.b	Sample ID	[BS7W2P]
5.c	Sample ID	[BS7W2R]

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851246

Generated By: pfe.levissc

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: 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: 10851246

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851246

Generated By: pfe.levissc

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: 10851246

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

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: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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: 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: 10851246

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 20-Feb-2021 02:17

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL - New
Unscheduled Visit**Form:** ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Not Started**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851246**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: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

Illness Details

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

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

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

Site No: 1085 **Site Name:** (1085) Ventavia Research Group

Subject No: 10851246 **Subject Initials:** ---

Generated By: pfe.lewissc **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: 10851246 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:22

Unplanned Assessments

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/27/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

Disposition - Follow-Up

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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: 10851246 **Subject Initials:** ---

Generated By: pfe.lewissc **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	[]
----	-----------	-----

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

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: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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	Oct/19/2020 UNK:UNK	YES	Repeating Pages

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure During Pregnancy]	
4.	Start Date Time:	Oct/19/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851246

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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: [N/A]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (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: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Medication Error

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

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: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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:	//

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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?	

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

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: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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?	

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

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: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

Vital Signs

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

Vital Signs Details

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** Unplanned Vaccination -
Unscheduled**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851246**Subject Initials:** ---**Generated By:** pfe.levisse**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: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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?	

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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: 10851246

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 - **Form:** DATE OF VISIT
Unscheduled

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

Site No: 1085 **Site Name:** (1085) Ventavia Research Group

Subject No: 10851246 **Subject Initials:** ---

Generated By: pfe.levissc **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: 10851246

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:** 10851246**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: 10851246

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1085 **Site Name:** (1085) Ventavia Research Group

Subject No: 10851246 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1085 **Site Name:** (1085) Ventavia Research Group

Subject No: 10851246 **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
----	---	---

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851246

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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 _____ []

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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: 10851246

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: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/27/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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
------	----------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-02-2020 17:42:31 (UTC-06:00) Central Time (US & Canada)	Katherine Benitez (pfe.kbenitez)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-02-2020 17:43:19 (UTC-06:00) Central Time (US & Canada)	Katherine Benitez (pfe.kbenitez)	Not Applicable

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
6	Nov-24-2020 14:54:13 (UTC-06:00) Central Time (US & Canada)	Banika Ervin (pfe.bervin)	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-03-2021 13:41:19 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition

Form: WITHDRAWAL OF CONSENT - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-03-2021 13:41:19 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-03-2021 13:41:37 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition

Form: DEATH DETAILS CODED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-03-2021 13:41:37 (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: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Chyann Stewart	N/A	Mar-03-2021 13:41:09 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Gregory Fuller	Approved	Jan-21-2021 14:07:36 (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	Dec-14-2020 12:01:03 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
----------------	-----	--	--	-----------------------------------

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** Investigator Signature -
Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature
History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Verified**Site No:** 1085**Site Name:** (1085) Ventavia Research Group**Subject No:** 10851246**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 10:22**Affidavit:**

N/A

Gregory Fuller	Approved	Dec-10-2020 16:19:52 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
----------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, Gregory Fuller, 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.

Banika Ervin	N/A	Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
--------------	-----	--	--	-----------------------------------

Affidavit:

N/A

Gregory Fuller	Approved	Nov-03-2020 09:39:44 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
----------------	----------	--	------	--------

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

Affidavit:

By my dated signature below, I, Gregory Fuller, 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.

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-02-2020 17:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 17:40:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: STAGE 3 COHORT S	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-02-2020 17:40:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: OBTAINED Date Written Consent Obtained Sep/2/2020	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-02-2020 17:40:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10851246	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-02-2020 17:40:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1987	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-02-2020 17:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-02-2020 17:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: HISPANIC OR LATI NO(A) OR OF SPA NISH ORIGIN	Initial Entry
---	-----------------	--	--	---------------

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

Date	Location	User	Value	Reason
Sep-02-2020 17:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: WHITE	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851246

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-02-2020 17:42:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Sep/2/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-02-2020 17:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Sep/2/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-02-2020 17:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-02-2020 17:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-02-2020 17:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Sep/2/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-02-2020 17:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 247.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-02-2020 17:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: LB	Initial Entry

4. Height:

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-02-2020 17:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 67.0	Initial Entry
---	-----------------	--	----------------------------	---------------

5. Unit:

Date	Location	User	Value	Reason
Sep-02-2020 17:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-02-2020 17:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 38.7	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-02-2020 17:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Record Identifier: Temperature: 97.4	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

			Temperatu F re Unit: Temperatu ORAL re Locatio CAVIT n:: Y	
--	--	--	---	--

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-02-2020 17:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-02-2020 17:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 97.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-02-2020 17:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: F	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-02-2020 17:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-02-2020 17:44:59 (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-02-2020 17:44:59 (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-02-2020 17:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Sep/2/2020	Initial Entry

4. Laboratory Name and Address (Derived)

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-02-2020 17:44:59 (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-02-2020 17:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-02-2020 17:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Sep-02-2020 17:44:59 (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-02-2020 17:44:59 (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-02-2020 17:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

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
Sep-02-2020 17:45:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Sep/2/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-02-2020 17:45:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 78304	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 09:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 09:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 09:34:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 09:33:48 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 09:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES Date of Collection: Sep/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 09:34:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID BP5BL : N	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 09:34:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BP5BLN	Initial Entry

5.b

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-03-2020 09:34:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID BNVT6 : 0	Initial Entry
---	-----------------	-------------------------	---	---------------

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 09:34:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BNVT60	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 09:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID BNVT6 : 1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 09:34:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BNVT61	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 09:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 09:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 09:34:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 09:33:54 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 09:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES Date of Collection: Sep/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 09:34:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BP5BJ6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 09:34:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BP5BJ6	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851246

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-02-2020 17:46:12 (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-02-2020 17:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-02-2020 17:46:12 (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
------	----------	------	-------	--------

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Sep-02-2020 17:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Sep/2/2020 14:00	Initial Entry
---	-----------------	--	--	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-02-2020 17:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-02-2020 17:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-02-2020 17:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-02-2020 17:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 17:46:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1085

Subject No: 10851246

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
Sep-02-2020 17:46:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-25-2020 12:25:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sep/25/2020	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-25-2020 12:26:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sep/25/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-25-2020 12:26:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Record Identifier:: Temperature: Temperature Unit: Temperature Location:: 1 98.1 F CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-25-2020 12:26:50 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: 1	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

& Canada)

2.a Temperature:

Date	Location	User	Value	Reason
Sep-25-2020 12:26:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: 98.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-25-2020 12:26:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-25-2020 12:26:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-25-2020 12:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-25-2020 12:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-25-2020 12:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sep/25/2020	Initial Entry

4. Laboratory Name and Address (Derived)

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Sep-25-2020 12:26:58 (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-25-2020 12:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-25-2020 12:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor- 113 Defined I dentifier: Test:: Choriogon adotropin Beta_PX11 3 Result:: NEGATIV E Not Done ::	Initial Entry

6.a Sponsor ID:

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Sep-25-2020 12:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-25-2020 12:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Choriogonadotropin B eta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-25-2020 12:26:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-25-2020 12:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-25-2020 12:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-25-2020 12:25:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-25-2020 12:25:34 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-25-2020 12:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES Date of Collection: Sep/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-25-2020 12:25:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BP9N88	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 12:25:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BP9N88	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-25-2020 12:28:17 (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
Sep-25-2020 12:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-25-2020 12:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-25-2020 12:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sep/25/2020 12:04	Initial Entry
---	-----------------	-------------------------	---	---------------

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-25-2020 12:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-25-2020 12:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-25-2020 12:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-25-2020 12:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 12:28:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1085 **Site Name:** (1085) Ventavia Research Group

Subject No: 10851246 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-27-2020 11:40:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Oct/27/2020	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1085 **Site Name:** (1085) Ventavia Research Group

Subject No: 10851246 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-27-2020 11:41:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-27-2020 11:41:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-27-2020 11:41:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 11:41:03 (UTC-06:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085 Site Name: (1085) Ventavia Research Group

Subject No: 10851246 Subject Initials: ---

Generated By: pfe.lewissc Generated Time (GMT): 29-Mar-2021 10:22

Central Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-27-2020 11:41:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES Date of Collection: Oct/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 11:41:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID BNZKP : 3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 11:41:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BNZKP3	Initial Entry

5.b

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1085 **Site Name:** (1085) Ventavia Research Group

Subject No: 10851246 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 10:22

Oct-27-2020 11:41:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID BS7W2 : P	Initial Entry
---	-----------------	-------------------------	--	---------------

5.b Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 11:41:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BS7W2P	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 11:41:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID BS7W2 : R	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 11:41:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BS7W2R	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1085 **Site Name:** (1085) Ventavia Research Group

Subject No: 10851246 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-27-2020 11:40:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Oct/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-27-2020 11:40:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-27-2020 11:40:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Form Created	

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-08-2021 11:58:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Jan-05-2021 11:22:25 (UTC-06:00)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Query 2: Answered	Faxed

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Central Time (US & Canada)				
Dec-22-2020 10:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL - please submit a Pregnancy update with Father information (age; smoke/alcohol /illicit drugs)
Dec-06-2020 09:03:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Dec-03-2020 16:17:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Correct as entered per reported by patient.
Dec-01-2020 14:22:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Per SAE meds section, subj had 1 cycle of Loestrin, ending 16OCT20 (with LMP starting 19OCT20). Prev birth

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

				control Yaz reported to end in ??OCT; however, please clarify if the Yaz end date (2nd to last cycle) would be in SEP2020.
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Exposure During Pregnancy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-30-2021 22:19:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	PG reported onset of 19Oct20
Jan-18-2021 14:37:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Query 4: Answered	Original value is correct
Jan-14-2021 22:54:16 (UTC-06:00) Central Time	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued: Opened	Clinical Thank you; however the most recent PG report

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)				update (09Jan21) still has PG start date of 16Nov20. Please submit an updated start date in the Event section of the report under Start Date/Time.
Jan-13-2021 11:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Query 4: Answered	That date is incorrect and was corrected in the Pregnancy forms sent this month.
Jan-11-2021 19:21:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued:Opened	Clinical Thank you. Query refers to the Event Start date, which is 19Oct20 on this AE CRF log. Pregnancy report (#2020459211) still has the 16Nov20 start date for the pregnancy, not 19Oct20
Jan-08-2021	ACV0PFEINFP6000	Angi Cox	Query 4: Answer	This is not

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

12:22:29 (UTC-06:00) Central Time (US & Canada)		(pfe.acox1)	ed	correct. The follow up form sent on 06Jan2021 clearly shows last LMP was 19Oct2020. 16Nov2020 was the date of the ultrasound.
Jan-08-2021 11:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical Event start date is 1st day of LMP (18Oct20); however, SAE report (update 06Jan21) has a different date of 16Nov20. Please update SAE report with 1st day of LMP in event section at ONSET date, if appropriate.
Jan-08-2021 11:52:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Jan-05-2021 11:26:38	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

(UTC-06:00) Central Time (US & Canada)				
Jan-05-2021 11:26:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Oct/19/2020 UN K:UNK	Transcription Error
Dec-15-2020 12:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissue d:Opened	CLINICAL Per CRF completion guidelines either 1st day of LMP (19Oct20) or estimated date of conception by ultrasound are used for Start date. As 16Nov20 is the date of + urine PG test (NOT used), please update to previous 1st day of LMP in both AE & SAE.
Dec-14-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answer ed	Changed Information

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Dec-14-2020 15:03:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Nov/16/2020 UN K:UNK	Changed Information
Dec-14-2020 13:45:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical Start date of event is 19Oct20 (1st day of LMP); however, SAE event start date is 16Nov20. Please review, harmonize reporting and update in the appropriate location.
Dec-14-2020 13:37:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Dec-14-2020 12:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Dec-14-2020 12:01:03 (UTC-06:00)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Data Entry: Oct/19/2020 UN K:UNK	Changed Information

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Central Time (US & Canada)				
Dec-10-2020 10:24:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissue d:Opened	CLINICAL - per C4591001 pregnancy reporting guideline Inj #1 on 02Sep and either conception or 1st day of LMP date falling after 02Sep, makes start of Exposure the latter date. In the SAE this date is 19Oct20; please harmonize on AE CRF
Dec-07-2020 09:06:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Nov/16/2020 UN K:UNK	Changed Information
Dec-07-2020 08:37:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Claudia Alonzo (pfe.calonzo)	Query 2: Answer ed	Positive pregnancy test was received on 16Oct2020 so date of known exposure would be 16Oct2020.

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

				start date updated to 16Oct2020
Dec-06-2020 09:11:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	CLINICAL SAE report states the 1st day of last menstrual period was 19Oct20, which per CRF completion guidelines can be used as start of PG; please update start in AE and SAE. (Note urine PG test was + on 16Nov20 per SAE)
Dec-04-2020 12:21:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Oct/16/2020 UN K:UNK	Changed Information
Dec-04-2020 12:21:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Query 2: Answered	Positive pregnancy test was received on 16Oct2020 so date of known exposure would be 16Oct2020.

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

				start date updated to 16Oct2020
Dec-01-2020 14:15:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Event of Exposure during PG start date is 19OCT20; however, the start date in the SAE report is still 16Nov2020. Please update as well with a SAE safety update
Dec-01-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-27-2020 12:49:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed per query
Nov-27-2020 12:49:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Oct/19/2020 UN K:UNK	Changed per query

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Nov-24-2020 22:41:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical Per recent all-site communication, the alternative guidance for PG Start date would be the first day of LMP (19Oct2020). Please review and update start date as appropriate.
Nov-24-2020 14:56:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	6wks 5 days was average gestational age given by ultrasound but is not accurate based on first day of LMP. True gestational age is and date is unknown.
Nov-23-2020 17:50:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - PG start date reported as 16Nov2020 [day of + pregnancy test]. However, optimal dating by OB US on 18Nov2020

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

				reports a 6 week 5 days pregnancy per the SAE narrative. Please review PG start date and update as appropriate.
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Nov/16/2020 UN K:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-24-2020 22:42:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-24-2020 14:57:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Changed data per query
Nov-23-2020 17:36:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - Reporting convention is Not Applicable for

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

				toxicity grading for pregnancy reporting
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-24-2020 14:54:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Not Applicable	Initial Entry
Nov-24-2020 14:54:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry:	Transcription Error
Nov-23-2020 16:48:05 (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.

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Nov-24-2020 22:38:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Nov-24-2020 14:36:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-24-2020 14:36:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-24-2020 14:36:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Transcription Error
Nov-23-2020 17:40:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL - For standard pregnancy reporting, reporting convention is Serious = NO. Any subsequent complication would undergo a separate assessment for serious.
Nov-23-2020 16:48:05	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Exposure

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-06:00) Central Time (US & Canada)				During Pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: YES Is this serious ev ent associated wi th congenital ano maly or birth def ect? NO Did this serious event result in de ath? NO Did this serious event require or prolong hospitali zation? NO	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

			<p>Did this serious event result in persistent or significant disability/in capacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	
--	--	--	--	--

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

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

Date	Location	User	Value	Reason
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

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

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Nov-24-2020 22:37:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-24-2020 14:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-24-2020 14:51:59 (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> N/A	Transcription Error
Nov-23-2020 17:46:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Causality is recorded as RELATED in AE CRF. Per SAE report the investigator considered there was NOT

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

				a reasonable possibility that exposure during pregnancy was related to any clinical trial procedure. Please update as appropriate.
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

& Canada)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-23-2020 16:48:05 (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
Nov-24-2020 22:44:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Nov-24-2020 22:43:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-24-2020 14:58:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 2: Answered	Correct as entered
Nov-24-2020	ACV0PFEINFP6000	auto query	Query 2: Opened	For AE

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

14:52:21 (UTC-06:00) Central Time (US & Canada)		(autoquery)		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".
Nov-24-2020 14:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-24-2020 14:52:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: UNKNOWN	Changed Information
Nov-24-2020 11:25:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Per CRF Completion Guidelines section 8.50.2.5, the outcome for an

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

				event of Exposure during Pregnancy is UNKNOWN (until end of pregnancy).
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 16:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: NO	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1085 **Site Name:** (1085) Ventavia Research Group

Subject No: 10851246 **Subject Initials:** ---

Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 13:41:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Jan/19/2021	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1085 **Site Name:** (1085) Ventavia Research Group

Subject No: 10851246 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

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

Date	Location	User	Value	Reason
Mar-03-2021 13:42:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Participant is willing to return for Vaccinat ion 3 Participant is: eligible per other protocol allowanc e(s) and confirme d to have received only placebo at V accination 1/2	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-03-2021 13:41:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Jan/19/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-03-2021 13:41:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT - 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: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Mar-03-2021 13:41:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - 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: 10851246

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Mar-03-2021 13:41:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-27-2020 11:40:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-02-2020 17:45:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-02-2020 17:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-23-2020 17:52:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed; further discussion of start date on AE CRF at event start
Nov-23-2020	ACV0PFEINFP6000	Kathryn	Query 1: Closed	Response

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.levisse

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

17:51:44 (UTC-06:00) Central Time (US & Canada)		Sewell (pfe.sewelk02)		satisfies query
Nov-23-2020 16:48:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: Answered	Data entered
Nov-23-2020 12:12:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 2: Answered	16Nov2020 is the date patient first discovered pregnancy so that is the start date given by patient
Nov-20-2020 11:28:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Exposure during PG start date reported on 16Nov20 (+ PG test date) in SAE; however; most accurate test is Gyn Ultrasound which had 6 wks/5 days pregnancy on 18Nov20. Please review, and update event start date.

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851246

Subject Initials: ---

Generated By: pfe.lewissc

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

Nov-20-2020 11:26:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Exposure during Pregnancy form (#2020459211) received; however, no event has been entered on the AE CRF; please update.
Oct-27-2020 11:40:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/27/2020	Initial Entry
Sep-02-2020 17:45:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/2/2020	Initial Entry
Sep-02-2020 17:43:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/2/2020	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851246

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-28-2020 14:30:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alicia Cruz (pfe.acruz)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3d8d\Final\Final On: 01-Apr-2021 04:37 (GMT)