

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/31/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[10851216]
2.	Birth Date:	(b) (6)/1959
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3d8c\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: 10851216

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	Aug/31/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

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

090177e196ae3d8c\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: 10851216

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/31/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypothyroidism]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Benign prostatic hyperplasia]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[vasectomy]
	Start Date:	UNK/UNK/1996
	Ongoing:	NO End Date: UNK/UNK/1996

090177e196ae3d8c\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: 10851216

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/31/2020
2.	Weight:	[189.0]
3.	Unit:	LB
4.	Height:	[67.0]
5.	Unit:	in
6.	Body Mass Index:	[29.6]

Vital Signs Details

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

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001	Form: RANDOMIZATION
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:03	Site Name: (1085) Ventavia Research Group
Site No: 1085	Subject Initials: ---
Subject No: 10851216	Generated Time (GMT): 29-Mar-2021 10:22
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Aug/31/2020
2.	Randomization Number:	[247120]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BKS5D]
5.b	Sample ID	[BLD25Y]
5.c	Sample ID	[BLD25Z]

090177e196ae3d8c\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: 10851216

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BKSR4W]
-----	-----------	----------

090177e196ae3d8c\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: 10851216

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:	Aug/31/2020 16:23
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d8c\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: 10851216

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
----	--	--

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

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/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/23/2020
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Vital Signs Details

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

Header Text: c4591001
Visit: V2_VAX2_L
Form Version: 22-Apr-2020 21:03
Site No: 1085
Subject No: 10851216
Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1085) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9N70]
-----	-----------	----------

090177e196ae3d8c\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: 10851216

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/23/2020 16:41
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

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

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	Oct/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNZKM1]
5.b	Sample ID	[BS7VYM]
5.c	Sample ID	[BS7VYN]

090177e196ae3d8c\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: 10851216

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: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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:	[]
----	------------------------	-----

090177e196ae3d8c\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: 10851216

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

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: 10851216

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	[]
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090177e196ae3d8c\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: 10851216

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?	
----	--	--

090177e196ae3d8c\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: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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:	

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: 10851216

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_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: 10851216

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

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

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 - 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: 10851216

Subject Initials: ---

Generated By: pfe.levissc

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

Unplanned Assessments

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

090177e196ae3d8c\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: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/21/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

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 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: 10851216

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	[]
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090177e196ae3d8c\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: 10851216

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	Left leg fracture of tibia/fibula	Oct/17/2020 UNK:UNK	NO End Date Time: Oct/18/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Fall in hole	Oct/17/2020 UNK:UNK	NO End Date Time: Oct/17/2020 UNK:UNK	Repeating Pages

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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)	[Left leg fracture of tibia/fibula]
4.	Start Date Time:	Oct/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/18/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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: [STEPPING IN HOLE]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020409576]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fall in hole]
4.	Start Date Time:	Oct/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/17/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Fall in hole]

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Medication Error

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

090177e196ae3d8c\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: 10851216

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

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

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Concomitant Medications

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

090177e196ae3d8c\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: 10851216

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

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae3d8c\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: 10851216

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

090177e196ae3d8c\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: 10851216
Generated By: pfe.levisse

Form: RADIATION TREATMENT
Form Status: Not Started
Site Name: (1085) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:22

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001	Form: TRANSFUSIONS
Visit: Logs - Unscheduled	Form Status: Not Started
Form Version: 22-Apr-2020 21:03	Site Name: (1085) Ventavia Research Group
Site No: 1085	Subject Initials: ---
Subject No: 10851216	Generated Time (GMT): 29-Mar-2021 10:22
Generated By: pfe.levisse	

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

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: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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?	

090177e196ae3d8c\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: 10851216 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 10:22

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

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/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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 local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/9/2021
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: 10851216

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: DEATH DETAILS CODED

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/12/2021
2.	Erroneous Visit	

Header Text: c4591001	Form: INFORMED CONSENT - FURTHER VACCINATION
Visit: V101_VAX3	Form Status: Data Complete, Frozen, Verified
Form Version: 10-Dec-2020 02:31	Site Name: (1085) Ventavia Research Group
Site No: 1085	Subject Initials: ---
Subject No: 10851216	Generated Time (GMT): 29-Mar-2021 10:22
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/12/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Feb/12/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR6WCV]
5.b	Sample ID	[BLD2CP]
5.c	Sample ID	[BLD2CR]

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR6WCP]
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090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/12/2021 12:13
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR6WH4]
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090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/3/2021 11:24
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

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: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	Form: CONTACT OUTCOME
Visit: V105_MONTH18	Form Status: Not Started
Form Version: 22-Apr-2020 21:04	Site Name: (1085) Ventavia Research Group
Site No: 1085	Subject Initials: ---
Subject No: 10851216	Generated Time (GMT): 29-Mar-2021 10:22
Generated By: pfe.lewissc	

Contact Outcome	
------------------------	--

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

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
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090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

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: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Aug-31-2020 17:40:12 (UTC-06:00) Central Time (US & Canada)	Katherine Benitez (pfe kbenitez)	Not Applicable

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - 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
7.a	Sep-01-2020 07:56:52 (UTC-06:00) Central Time (US & Canada)	Angi Cox (pfe.acox1)	NCS

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - 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
7.a	Sep-01-2020 07:56:52 (UTC-06:00) Central Time (US & Canada)	Angi Cox (pfe.acox1)	NCS

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001	Form: VITAL SIGNS - BASELINE - Comments
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 21-Aug-2020 02:51	Site Name: (1085) Ventavia Research Group
Site No: 1085	Subject Initials: ---
Subject No: 10851216	Generated Time (GMT): 29-Mar-2021 10:22
Generated By: pfe.levisse	

[Back to Form](#)

Item	Date	User	Comment
7.a	Sep-01-2020 07:56:52 (UTC-06:00) Central Time (US & Canada)	Angi Cox (pfe.acox1)	NCS

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Feb-25-2021 08:19:00 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
1	Feb-25-2021 08:19:00 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Feb-25-2021 08:21:53 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001	Form: DEATH DETAILS CODED - Comments
Visit: Disposition	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:03	Site Name: (1085) Ventavia Research Group
Site No: 1085	Subject Initials: ---
Subject No: 10851216	Generated Time (GMT): 29-Mar-2021 10:22
Generated By: pfe.levisse	

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Item	Date	User	Comment
1	Feb-25-2021 08:21:53 (UTC-06:00) Central Time (US & Canada)	Chyann Stewart (pfe.cstewart)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Feb-12-2021 15:46:24 (UTC-06:00) Central Time (US & Canada)	Katherine Benitez (pfe kbenitez)	Not Applicable

090177e196ae3d8c\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: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Banika Ervin	N/A	Feb-12-2021 12:56:19 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Gregory Fuller	Approved	Nov-05-2020 09:25:37 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, GregoryFuller, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Katherine Benitez	N/A	Oct-30-2020 13:50:04 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Gregory Fuller	Approved	Oct-30-2020 12:42:23 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, GregoryFuller, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3d8c\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: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

Katherine Benitez	N/A	Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Gregory Fuller	Approved	Oct-28-2020 19:08:21 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, GregoryFuller, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-31-2020 17:39:11 (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
Aug-31-2020 17:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Consent Was:

Date	Location	User	Value	Reason
Aug-31-2020 17:39:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: OBTAINED Date Written Consent Obtained Aug/31/2020	Initial Entry

090177e196ae3d8c\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: 10851216

Generated By: pfe.levissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-31-2020 17:38:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10851216	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-31-2020 17:38:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1959	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-31-2020 17:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-31-2020 17:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 17:39:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: WHITE	Initial Entry

090177e196ae3d8c\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: 10851216

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

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-31-2020 17:40:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae3d8c\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: 10851216

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-31-2020 17:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Aug/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-31-2020 17:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-31-2020 17:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d8c\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: 10851216

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1.a

Date	Location	User	Value	Reason
Aug-31-2020 17:41:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: hypertension Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 17:41:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 17:41:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: hypertension	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 17:41:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: UNK/UNK/2015	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 17:41:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES	Initial Entry

1.b

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-31-2020 17:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: hypothyroidism Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 17:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 17:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: hypothyroidism	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 17:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: UNK/UNK/1990	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 17:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-01-2020 07:59:35 (UTC-06:00) Central	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Line/MH Number: 3	Transcription Error

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Time (US & Canada)			mber: Medical History Term: Benign prostatic hyperplasia Start Date: UNK/UNK/2018 Ongoing: YES	
Aug-31-2020 17:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 mber: Medical History Term: Benign prostatic hyperplasia Start Date: UNK/UNK/2020 Ongoing: YES	Initial Entry

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 17:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 17:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Benign prostatic hyperplasia	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 07:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-01-2020 07:59:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: UNK/UNK/2018	Transcription Error
Aug-31-2020 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 31/Aug/2020. Please review and update as appropriate.
Aug-31-2020 17:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: UNK/UNK/2020	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 17:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
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090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Aug-31-2020 17:43:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: vasectomy Start Date: UNK/UNK/1996 Ongoing: NO End Date: UNK/UNK/ 1996	Initial Entry
---	-----------------	-------------------------	--	---------------

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 17:43:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 17:43:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: vasectomy	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 17:43:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: UNK/UNK/1996	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 17:43:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO End Date: UNK/UNK/1996	Initial Entry

090177e196ae3d8c\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: 10851216

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-31-2020 17:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Aug/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-31-2020 17:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 189.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 17:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-31-2020 17:44:08 (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
Aug-31-2020 17:44:08 (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
Aug-31-2020 17:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29.6	Initial Entry

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

7.a

Date	Location	User	Value	Reason
Aug-31-2020 17:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Record Identifier: 1 : Temperature: 96.9 Temperature Unit F : Temperature Loca ORAL CAV tion:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 17:44:08 (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 05:51:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Closed	Closed by DM: PM.
Sep-01-2020 07:57:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Query 1: Answered	Added into comments.
Sep-01-2020 05:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Reissued:Opened	DM 1: Thank you for your response. Please state if this is clinically significant or not.
Aug-31-2020 17:47:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe kbenitez)	Query 1: Answered	Original value is correct
Aug-31-2020 17:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.9 F is outside of Normal Range 97 - 99.5 F.
Aug-31-2020 17:44:08 (UTC-06:00) Central	ACV0PFEINFP6000	Katherine Benitez	Data Entry: 96.9	Initial Entry

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Time (US & Canada)

(pfe.kbenitez)

7.a Unit:

Date	Location	User	Value	Reason
Aug-31-2020 17:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-31-2020 17:44:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-31-2020 17:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Aug/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-31-2020 17:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 247120	Initial Entry

090177e196ae3d8c\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: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-31-2020 17:47:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 17:47:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 07:56:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-01-2020 05:32:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 17:47:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 17:47:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

090177e196ae3d8c\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: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-01-2020 07:56:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> Sample ID: BKS5D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 07:56:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> BKS5D	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 07:56:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> Sample ID: BLD25Y	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 07:56:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> BLD25Y	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 07:56:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> Sample ID: BLD25Z	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 07:56:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> BLD25Z	Initial Entry

090177e196ae3d8c\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: 10851216

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-31-2020 17:47:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 17:47:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 07:55:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-01-2020 05:32:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 17:47:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 17:47:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES Date of Collection: Aug/31/2020	Initial Entry

5.a

090177e196ae3d8c\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: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-01-2020 07:55:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> Sample ID: BKS4W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 07:55:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> BKS4W	Initial Entry

090177e196ae3d8c\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: 10851216

Generated By: pfe.lewiss

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-31-2020 17:49:03 (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
Aug-31-2020 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-31-2020 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-31-2020 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Aug/31/2020 16:23	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-31-2020 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-31-2020 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: LEFT	Initial Entry

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Aug-31-2020 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-31-2020 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 17:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES	Initial Entry

090177e196ae3d8c\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: 10851216

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-31-2020 17:49:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-24-2020 09:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> Sep/23/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-24-2020 09:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sep/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-24-2020 09:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Record Identifier:: 1 Temperature: 98.1 Temperature Unit: F Temperature Locat ORAL CAVI ion:: TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-24-2020 09:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-24-2020 09:31:56 (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-24-2020 09:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-24-2020 09:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d8c\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: 10851216

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-24-2020 07:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-24-2020 07:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-24-2020 07:37:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 07:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-24-2020 07:37:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES Date of Collection: Sep/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-24-2020 07:37:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BP9N70	Initial Entry

090177e196ae3d8c\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: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 07:37:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	<u>Data Entry:</u> BP9N70	Initial Entry

090177e196ae3d8c\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: 10851216

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-24-2020 09:32:21 (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-24-2020 09:32:21 (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-24-2020 09:32:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-24-2020 09:32:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sep/23/2020 16:41	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-24-2020 09:32:21 (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-24-2020 09:32:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: LEFT	Initial Entry

090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Sep-24-2020 09:32:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-24-2020 09:32:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-24-2020 09:32:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-21-2020 09:48:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Oct/21/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-21-2020 09:48:21 (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-21-2020 09:48:21 (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-21-2020 09:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 09:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-21-2020 09:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: YES Date of Collection: Oct/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 09:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BNZKM1	Initial Entry

090177e196ae3d8c\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: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 09:48:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BNZKM1	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-21-2020 09:48:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BS7VYM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 09:48:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BS7VYM	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 09:48:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Sample ID: BS7VYN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-21-2020 09:48:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: BS7VYN	Initial Entry

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-21-2020 09:47:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Oct/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-21-2020 09:47:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-21-2020 09:47:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1085) Ventavia Research Group

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1. Category:

Date	Location	User	Value	Reason
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-21-2020 15:04:44 (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
Nov-03-2020 18:41:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 2: Closed	Response satisfies query
Oct-29-2020 16:06:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe kbenitez)	Query 2: Answered	Changed data per query
Oct-29-2020 12:07:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe frantu)	Query 1: Closed	this should be an acceptable discrepancy now between ARGUS and clinical DB
Oct-27-2020 20:38:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 2: Opened	Clin: Was this injury the result of a fall or trip (involving a hole)? Per section 8.49.2.2 of CRF completion requirements when a fall results in an injury, both the injury and the fall should be recorded as AEs. Please evaluate and update as appropriate

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1085**Subject No:** 10851216**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1085) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

Oct-27-2020 01:00:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Candidate	SAE RECON: For Clinical review
Oct-26-2020 13:29:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Query 1: Answered	Can not split term. Correct as is
Oct-24-2020 08:10:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Opened	SAE RECON 1: The term match in both database.Howevem,the term is coding to 2 PTs in Safety. Please review and consider to split the terms and record as separate events in AE CRF.
Oct-22-2020 22:29:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Candidate	SAE RECON: For clinical review of coding discrepancy
Oct-22-2020 07:36:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-22-2020 07:36:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Left leg fracture of tibia/fibula	Transcription Error
Oct-22-2020 06:23:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020409576,the term in Safety database was reported as 'left leg fracture of tibia/fibula',however recorded as 'LEFT LEG Fracture' in AE CRF. Please confirm correct term. If safety update is required, please submit a follow up form
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: LEFT LEG FRACTURE	Initial Entry

4. Start Date Time:

Header Text: c4591001

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Subject No: 10851216

Generated By: pfe.levisse

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Form Status: Data Complete, Locked, Frozen

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Oct/17/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO End Date Time: Oct/18/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-26-2020 16:57:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed, will follow for SAE update with the requested COVID test info
Oct-26-2020 15:22:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Query 2: Answered	follow up sae submitted.
Oct-23-2020 09:55:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - COVID testing has not been reported in the SAE submitted to safety. Please submit a

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Subject Initials: ---

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				follow-up SAE form [#2020409576] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Oct-22-2020 06:19:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE LEFT LEG FRACTURE: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe kbenitez)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p>	Initial Entry

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Subject No: 10851216

Generated By: pfe.levisse

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			NO	
			Other medically important serious event	
			NO	

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

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

Date	Location	User	Value	Reason
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-26-2020 17:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (pfe.banchp)	Query 1: Closed	per site response.
Oct-26-2020 15:22:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Query 1: Answered	The patient did not experience a fall and them broke their leg. The patient stepped in a hole which was unexpected and then broke their leg.
Oct-23-2020 19:16:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (pfe.banchp)	Query 1: Reissued:Opened	GPDCLIN: Thank you for your response. Please reference CRF completion requirements section 8.49.2.2 and update as applicable if the subject experienced a fall. Thank you.
Oct-23-2020 15:40:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Query 1: Answered	Patient stepped in a hole in their backyard which resulted in breaking their leg. It was not just a fall. cause of

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1085**Subject No:** 10851216**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1085) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

				the broken leg was stepping in a large hole unexpectedly.
Oct-23-2020 08:21:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (pfe.banchp)	Query 1: Reissued:Opened	GPDCLIN: Thank you for our response. Please kindly confirm if the subject experienced or did not experience a fall and update as applicable per section 8.49.2.2 of CRF completion requirements. Otherwise please clarify. Thank you.
Oct-22-2020 16:17:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-22-2020 16:17:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> STEPPING IN HOLE	Changed Information
Oct-22-2020 15:24:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (pfe.banchp)	Query 1: Opened	GPDCLIN: Per CRF completion requirements (8.49.2.2) when a fall results in an injury, both the injury and the fall should be recorded as AEs. Please review and update as applicable. Otherwise, please clarify.
Oct-21-2020 15:33:13	ACV0PFEINFP6000	Katherine	Data Entry:	Changed

Header Text: c4591001

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Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

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(UTC-06:00) Central Time (US & Canada)		Benitez (pfe.kbenitez)	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> FALL	Information
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-26-2020 16:55:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-26-2020 15:16:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-26-2020 15:16:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES	Changed Information

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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Oct-23-2020 09:56:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - SAE report states surgery to place screws/plate was performed on 18 Oct 2020; please review and update non-Drug Treatment received if appropriate
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 15:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-22-2020 06:19:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020409576	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1085**Subject No:** 10851216**Generated By:** pfe.lewissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1085) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-30-2020 13:50:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Fall in hole	Changed Information
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Fall	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Oct/17/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO End Date Time: Oct/17/2020 UNK:UNK	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER If Other, specify: Fall in hole	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae3d8c\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: 10851216

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-29-2020 16:06:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: NO	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 11:37:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Data Entry: Jan/9/2021	Transcription Error
Feb-12-2021 12:56:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Jan/15/2021	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1085**Subject No:** 10851216**Generated By:** pfe.levissc**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History**Form Status:** Data Complete, Frozen**Site Name:** (1085) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Feb-25-2021 08:18:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-14-2021 23:53:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-12-2021 12:56:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-12-2021 12:56:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-10-2021 15:22:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_36
Mar-10-2021 11:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Angi Cox (pfe.acox1)	Query 1: An swere d	Changed data per query
Mar-10-2021 05:34:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Rei ssued: Opene d	DM: DOV CRF at Revax Cont is unfrozen, kindly review and update.
Mar-09-2021 12:51:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: An swere d	Rvax cont page still needs to be unfrozen
Mar-05-2021 00:10:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Rei ssued: Opene d	DM: Page unfreeze kindly verify and consider updating correct data. Thank you.
Mar-04-2021 13:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Banika Ervin (pfe.bervin)	Query 1: An swere d	On site side, revax cont page is still frozen. Please unfreeze.

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1085**Subject No:** 10851216**Generated By:** pfe.levisse**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1085) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

Mar-01-2021 23:36:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Reissued: Opened	DM: Page unfreeze kindly verify and consider updating correct data. Thank you.
Mar-01-2021 15:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Query 1: Answered	Please unfreeze Revax Cont so query can be updated.
Feb-26-2021 17:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7479041;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Feb-25-2021 08:18:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry : Jan/9/ 2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-25-2021 08:18:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Feb-25-2021 08:19:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Feb-25-2021 08:21:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Chyann Stewart (pfe.cstewart)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-12-2021 15:45:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Feb/12/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Consent Was:

Date	Location	User	Value	Reason
Feb-12-2021 15:45:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: OBTAINED Date Written Consent Obtained Feb/12/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-12-2021 15:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Feb/12/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-12-2021 15:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-12-2021 15:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-12-2021 15:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-12-2021 15:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 15:58:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-15-2021 05:54:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-12-2021 15:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-12-2021 15:47:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES Date of Collection: Feb/12/2021	Initial Entry

5.a

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Mar-03-2021 15:58:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Sample ID: BR6WCV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 15:58:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: BR6WCV	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-03-2021 16:00:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Sample ID: BLD2CP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 16:00:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: BLD2CP	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-03-2021 16:00:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Sample ID: BLD2CR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 16:00:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: BLD2CR	Initial Entry

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Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-12-2021 15:47:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-12-2021 15:47:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 16:00:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-15-2021 05:54:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-12-2021 15:47:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-12-2021 15:47:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES Date of Collection: Feb/12/2021	Initial Entry

5.a

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Mar-03-2021 16:00:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: Sample ID: BR6WCP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 16:00:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Linda Langdon (pfe.llangdon)	Data Entry: BR6WCP	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-12-2021 15:48:17 (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
Feb-12-2021 15:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-12-2021 15:48:17 (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
Feb-12-2021 15:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Feb/12/2021 12:13	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-12-2021 15:48:17 (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
Feb-12-2021 15:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: LEFT	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Feb-12-2021 15:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-12-2021 15:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-12-2021 15:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-12-2021 15:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 15:48:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: YES	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1085

Subject No: 10851216

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 07:57:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Michael Johnson (pfe mjohanson3)	Data Entry: Mar/3/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-05-2021 07:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-05-2021 07:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-05-2021 08:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 07:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-05-2021 07:59:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Michael Johnson (pfe mjohanson3)	Data Entry: YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-05-2021 08:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Michael Johnson (pfe mjohanson3)	Data Entry: Sample ID: BR6WH4	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 08:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Michael Johnson (pfe mjohanson3)	Data Entry: BR6WH4	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-05-2021 08:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Michael Johnson (pfe mjohnson3)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-05-2021 08:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-05-2021 08:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-05-2021 08:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Michael Johnson (pfe mjohnson3)	Data Entry: Mar/3/2021 11:24	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-05-2021 08:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-05-2021 08:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Michael Johnson (pfe mjohnson3)	Data Entry: LEFT	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1085

Subject No: 10851216

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Mar-05-2021 08:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-05-2021 08:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-05-2021 08:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-05-2021 08:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-05-2021 08:01:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Michael Johnson (pfe mjohanson3)	Data Entry: YES	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1085

Subject No: 10851216

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1085) Ventavia Research Group

Subject Initials: ---

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-21-2020 09:47:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-31-2020 17:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-31-2020 17:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-21-2020 09:47:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/21/2020	Initial Entry
Aug-31-2020 17:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry
Aug-31-2020 17:40:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae3d8c\Final\Final On: 01-Apr-2021 04:37 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1085

Site Name: (1085) Ventavia Research Group

Subject No: 10851216

Subject Initials: ---

Generated By: pfe.lewissc

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-28-2020 13:42:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Benitez (pfe.kbenitez)	Data Entry: Click Here to Enable	Initial Entry