

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[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

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001	Form: MAIN INFORMED CONSENT
Visit: COHORT_SELECTION	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/27/2020

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10151134]
2.	Birth Date:	(b) (6)/1965
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001	Form: DATE OF VISIT
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Aug/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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	Form: DISPOSITION - SCREENING
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:03	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/27/2020
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: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Childhood asthma]
	Start Date:	UNK/UNK/1975
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Acid reflux]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vertigo]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/27/2020
2.	Weight:	[165.0]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[22.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (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: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Aug/27/2020
2.	Randomization Number:	[70275]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BLD08S]
5.b	Sample ID	[BLD08T]
5.c	Sample ID	[BM8F23]
5.d	Sample ID	[BM8F24]
5.e	Sample ID	[BM8F25]

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8F1W]
-----	-----------	----------

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/27/2020 14:39
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	------------------------------------------------------------------	------------------------------------------------------------

Header Text: c4591001	Form: DATE OF VISIT
Visit: V2_VAX2_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Sep/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Vital Signs

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

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	Temperature:	Not Done _____ []	Comments
	Unit:	Not Done _____	Comments
	Temperature Location:	Not Done _____	Comments

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ []
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090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Vaccination

1.	Was there a temporary delay of vaccination?	Not Done _____	Comments
2.	Treatment Name	Not Done _____ []	Comments
3.	Formulation:	Not Done _____	Comments
4.	Dose Date Time:	Not Done _____ //	Comments
5.	Anatomical Location:	Not Done _____	Comments
6.	Body Side:	Not Done _____	Comments
7.	Route:	Not Done _____	Comments
8.	Actual Dose:	Not Done _____ []	Comments
9.	Unit:	Not Done _____	Comments
10.	Timeframe Subject Was Observed	Not Done _____	Comments
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done _____	Comments

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001	Form: DATE OF VISIT
Visit: V3_MONTH1_POSTVAX2_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Nov/6/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/6/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BSH17L]
5.b	Sample ID	[BSH17D]
5.c	Sample ID	[BSH17F]
5.d	Sample ID	[BRFKGB]

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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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090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/6/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Worsening and continuing episode of Vertigo	Aug/28/2020 UNK:UNK	NO End Date Time: Dec/21/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Headache	Aug/28/2020 UNK:UNK	NO End Date Time: Sep/1/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Nausea	Aug/28/2020 UNK:UNK	NO End Date Time: Sep/1/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Diarrhea	Aug/28/2020 UNK:UNK	NO End Date Time: Aug/28/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	Injection site pain	Dec/21/2020 UNK:UNK	NO End Date Time: Dec/22/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Chills	Jan/13/2021 20:00	NO End Date Time: Jan/15/2021 UNK:UNK	Repeating Pages
7.	ADVERSE EVENT	7	Injection site pain	Jan/13/2021 20:00	NO End Date Time: Jan/15/2021 UNK:UNK	Repeating Pages
8.	ADVERSE EVENT	8	Headache	Jan/14/2021 03:00	NO End Date Time: Jan/15/2021 UNK:UNK	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening and continuing episode of Veritgo]
4.	Start Date Time:	Aug/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/21/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
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

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Adverse Event Report

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

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Adverse Event Report

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Adverse Event Report

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Dec/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/22/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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Header Text: c4591001

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Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chills]
4.	Start Date Time:	Jan/13/2021 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/15/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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

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Header Text: c4591001

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Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Jan/13/2021 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/15/2021 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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

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Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Jan/14/2021 03:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/15/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
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

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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15.	Serious Adverse Event Number: For Pfizer Use Only	[]
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Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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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	[]

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Fluzone Quadrivalent	Sep/28/2020	Repeating Pages

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Fluzone Quadrivalent]
5.	Date:	Sep/28/2020

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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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?	

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Vital Signs

1.	Date:	//
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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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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?	

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001	Form: CONTACT OUTCOME - MONTH 1
Visit: Unplanned Vaccination - Unscheduled	Form Status: Not Started
Form Version: 10-Oct-2020 15:57	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levisse	

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

Header Text: c4591001	Form: CONTACT OUTCOME - MONTH 6
Visit: Unplanned Vaccination - Unscheduled	Form Status: Not Started
Form Version: 10-Oct-2020 16:01	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levisse	

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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001	Form: DATE OF VISIT
Visit: V101_VAX3	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Dec/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/21/2020
----	--------------	----------------------------------------------------------

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/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	[BSN5CN]
5.b	Sample ID	[BSN5CW]
5.c	Sample ID	[BSN5CX]
5.d	Sample ID	[BRFKMW]

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/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	[BRFKMR]
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090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/21/2020 13:20
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

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/14/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

Death Details

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

Cause of Death

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

Header Text: c4591001	Form: DATE OF VISIT
Visit: V102_VAX4	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/13/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/13/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR707N]
-----	-----------	----------

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001	Form: VACCINATION
Visit: V102_VAX4	Form Status: Data Complete, Frozen, Verified
Form Version: 10-Dec-2020 02:26	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/13/2021 12:45
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001	Form: DATE OF VISIT
Visit: V103_MONTH1	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/10/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	Form: CONTACT OUTCOME
Visit: V104_MONTH6	Form Status: Not Started
Form Version: 22-Apr-2020 21:04	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levisse	

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

Header Text: c4591001	Form: DATE OF VISIT
Visit: V105_MONTH18	Form Status: Not Started
Form Version: 22-Apr-2020 21:02	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levissc	

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: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levisse	

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

Header Text: c4591001
Visit: FURTHER_VACCINATION_EOT - Unscheduled
Form: DISPOSITION - TREATMENT
Form Version: 20-Feb-2021 02:26
Form Status: Data Complete, Verified
Site No: 1015
Site Name: (1015) Boston Medical Center
Subject No: 10151134
Subject Initials: ---
Generated By: pfe.levisse
Generated Time (GMT): 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Feb/10/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001	Form: SUBJECT STATUS
Visit: Subject Status - Unscheduled	Form Status: Data Complete, Verified
Form Version: 22-Apr-2020 21:03	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Subject Status		
1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/6/2020

Header Text: c4591001	Form: CASEBOOK SIGNATURE FORM
Visit: Investigator Signature - Unscheduled	Form Status: Data Complete, Signed, Verified
Form Version: 22-Apr-2020 21:04	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151134	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Elizabeth Barnett	Approved	Mar-11-2021 10:57:31 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
Form	Aug-27-2020 16:37:46 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Applicable

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
Form	Sep-22-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
1	Sep-22-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Done

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
2.a	Sep-22-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
2.a	Sep-22-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Done

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
2.a	Sep-22-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
Form	Sep-22-2020 12:46:35 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Done

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
1	Sep-22-2020 12:46:35 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[Back to Form](#)

Item	Date	User	Comment
2	Sep-22-2020 12:46:35 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Done

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[Back to Form](#)

Item	Date	User	Comment
3	Sep-22-2020 12:46:35 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
4	Sep-22-2020 12:46:35 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Done

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
Form	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[Back to Form](#)

Item	Date	User	Comment
1	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

[Back to Form](#)

Item	Date	User	Comment
2	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
3	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
4	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
5	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
6	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
7	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
8	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
9	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
10	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Item	Date	User	Comment
11	Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Due to history of vertigo and ongoing episode of vertigo since last vaccination, study doctor decided to wait until episode resolves. <hr/> Not Done

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION -
Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-21-2020 13:42:52 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Elizabeth Barnett	Approved	Mar-11-2021 10:57:31 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, ElizabethBarnett, 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.

Taylor Stannard	N/A	Feb-12-2021 13:04:21 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Elizabeth Barnett	Approved	Jan-22-2021 15:11:36 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, ElizabethBarnett, 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.

Taylor Stannard	N/A	Jan-21-2021 12:26:03 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Elizabeth Barnett	Approved	Jan-20-2021 19:53:50 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151134**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**Affidavit:**

By my dated signature below, I, ElizabethBarnett, 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.

Taylor Stannard	N/A	Dec-21-2020 13:41:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Elizabeth Barnett	Approved	Nov-13-2020 16:18:20 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, ElizabethBarnett, 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.

Taylor Stannard	N/A	Nov-11-2020 15:30:25 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Elizabeth Barnett	Approved	Nov-09-2020 10:38:07 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, ElizabethBarnett, 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.

Taylor Stannard	N/A	Nov-07-2020 14:08:36 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Affidavit:

N/A

Elizabeth Barnett	Approved	Nov-06-2020 19:33:28 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, ElizabethBarnett, 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.

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-27-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 16:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-27-2020 16:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: OBTAINED Date Written Consent Obtained Aug/27/2020	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Subject ID

Date	Location	User	Value	Reason
Aug-27-2020 16:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10151134	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-27-2020 16:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1965	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-27-2020 16:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-27-2020 16:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	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-27-2020 16:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: WHITE	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-27-2020 16:37:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/27/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-27-2020 16:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-27-2020 16:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-27-2020 16:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1015**Subject No:** 10151134**Generated By:** pfe.levisse**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Aug-27-2020 16:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Childhood asthma Start Date: UNK/UNK/1975 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 16:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 16:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Childhood asthma	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 16:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: UNK/UNK/1975	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 16:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Aug-27-2020 16:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

			Medical History Term: Acid reflux Start Date: UNK/UNK/2000 Ongoing: YES	
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I.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 16:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Acid reflux	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: UNK/UNK/2000	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-22-2020 12:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Line/MH Number: 3 Medical History Term: Vertigo Start Date: UNK/UNK/2012 Ongoing: YES	Transcription Error
Sep-22-2020 12:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

			Medical History Term: Start Date: UNK/UNK/2018 Ongoing: YES	
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 12:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Vertigo	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 12:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: UNK/UNK/2012	Transcription Error
Sep-22-2020 12:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: UNK/UNK/2018	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 12:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Date:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/27/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 165.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 72.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22.4	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

Aug-27-2020 16:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-27-2020 16:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-27-2020 16:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/27/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-27-2020 16:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 70275	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151134**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-27-2020 21:31:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-27-2020 21:31:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 21:31:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 21:31:41 (UTC-05:00) Eastern 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-27-2020 21:31:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Aug/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 21:31:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BLD08S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 21:31:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BLD08S	Initial Entry

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
 Form Version: 22-Apr-2020 21:03
 Site No: 1015
 Subject No: 10151134
 Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
 Audit Trail History
 Form Status: Data Complete, Locked, Frozen, Verified
 Site Name: (1015) Boston Medical Center
 Subject Initials: ---
 Generated Time (GMT): 29-Mar-2021 04:21

5.b

Date	Location	User	Value	Reason
Aug-27-2020 21:32:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BLD08T	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 21:32:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BLD08T	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-27-2020 21:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8F23	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 21:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8F23	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-27-2020 21:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8F24	Transcription Error
Aug-27-2020 21:32:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8F244	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

5.d Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 21:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-27-2020 21:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8F24	Transcription Error
Aug-27-2020 21:32:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Aug-27-2020 21:32:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8F244	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-27-2020 21:32:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8F25	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 21:32:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8F25	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (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:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151134**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-27-2020 21:33:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-27-2020 21:33:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 21:33:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 21:33:12 (UTC-05:00) Eastern 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-27-2020 21:33:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Aug/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 21:33:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8F1W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 21:33:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8F1W	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:04
Site No: 1015
Subject No: 10151134
Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1015) Boston Medical Center
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:21

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-27-2020 16:40:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-27-2020 16:40:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-27-2020 16:40:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-27-2020 16:40:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/27/2020 14:39	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-27-2020 16:40:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-27-2020 16:40:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

Aug-27-2020 16:40:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-27-2020 16:40:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSER VATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 16:40:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-27-2020 16:41:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-22-2020 12:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/17/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Date:

Date	Location	User	Value	Reason
Sep-22-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-22-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Record Identifier:: Not Done Temperature: Not Done Temperature Unit: Not Done Temperature Location:: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-22-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-22-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-22-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-22-2020 12:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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1. Data Origin

Date	Location	User	Value	Reason
Sep-22-2020 12:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-22-2020 12:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-22-2020 12:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:47:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Not Done	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-07-2020 15:21:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laurie Hawes (pfe.hawesl01)	Query 1: Closed	Response satisfies query
Nov-07-2020 14:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	PI made decision to not have subject receive second dose due to worsening vertigo. Subject did not attend second visit, and after rep-contacting they chose to come back for their visit 3
Nov-07-2020 03:31:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Opened	PDQ: DOV at this visit is out of window (15 day) from DOV (17/Sep/2020) at V2. Please either update DOV or confirm whether visit is out of window due to temporary delay of vaccination/ else provide details as appropriate.
Nov-06-2020 15:23:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Nov/6/2020	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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1. Data Origin

Date	Location	User	Value	Reason
Nov-07-2020 14:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-07-2020 14:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-07-2020 14:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Nov/6/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-07-2020 14:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSH17L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-07-2020 14:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BSH17L	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-07-2020 14:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSH17D	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

5.b Sample ID

Date	Location	User	Value	Reason
Nov-07-2020 14:11:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BSH17D	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-07-2020 14:11:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BSH17F	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-07-2020 14:11:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BSH17F	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-07-2020 14:15:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BRFKGB	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Nov-07-2020 14:15:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BRFKGB	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151134**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-06-2020 15:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Nov/6/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-06-2020 15:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-12-2020 10:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	Response satisfies query
Nov-12-2020 10:05:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-12-2020 10:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Nov-12-2020 10:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Nov-12-2020 10:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: ADVERSE EVENT	New Information
Nov-12-2020 02:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 3: Reissued:Opened	DM: "Specify Status" (item4) is not required if Status is "PHYSICIAN DECISION" at (item 3). Please review and update accordingly.
Nov-11-2020 15:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Reissued:Opened	CLINQUERY: If the event of Worsening Vertigo was involved

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151134**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

				in the decision to cease treatment, please consider updating this EOT status to be ADVERSE EVENT to link
Nov-11-2020 15:30:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 3: Answered	Changed data per query
Nov-11-2020 15:30:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 2: Answered	Changed data per query
Nov-11-2020 15:30:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is PHYSICIAN DECISION but "Specify Status" is Provided.
Nov-11-2020 09:14:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Opened	CLINQUERY: Please clarify the conditions leading to the decision to discontinue treatment. If any of the adverse events contributed to this decision, they should be indicated and status field updated
Nov-07-2020 15:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Laurie Hawes (pfe.hawesl01)	Query 1: Closed	Response satisfies query
Nov-07-2020 14:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-07-2020 14:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: PHYSICIAN DECISION	New Information
Nov-07-2020 09:12:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	Subject has not received vaccination 2, hence status cannot be COMPLETED. Please verify and update as appropriate. Else clarify.
Nov-06-2020 15:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

4. Specify Status:

Date	Location	User	Value	Reason
Nov-12-2020 10:05:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry:	New Information
Nov-11-2020 15:30:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Due to worsening vertigo post vaccine one, PI decided that second dose should be skipped for safety.	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

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Form Status:

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-24-2020 05:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 4: Closed	Closed as data updated.
Sep-23-2020 10:02:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Sep-23-2020 10:02:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Worsening and continuing episode of Veritgo	New Information
Sep-23-2020 04:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 4: Opened	The AE Episode of Veritgo was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

				conditions should only be reported as AEs if they worsen. "[naikp09 SDQ=11049]"
Sep-22-2020 15:41:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Sep-22-2020 15:36:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Event is no longer a SAE
Sep-22-2020 12:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Sep-22-2020 12:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Sep-22-2020 12:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Episode of Vertigo	New Information
Sep-22-2020 11:51:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued: Opened	CLINQUERY SAE notes history of Vertigo 2x; please consider an update to Medical History now that this is known
Sep-22-2020 11:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINQUERY please update SAE with start/stop dates for Med Hx of Vertigo, and update narrative with years since most recent episode (currently reads "last episode

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1015**Subject No:** 10151134**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

				of vertigo years ago")
Sep-18-2020 15:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 2: Answered	Please unfreeze medical history so I can add, thank you!
Sep-18-2020 09:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINQUERY SAE notes history of VERTIGO 2x over 10 years ago; please consider an update to Medical History
Sep-14-2020 10:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Sep-12-2020 15:47:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify VERTIGO as follows...Should spelling be VERTIGO? If so,edit. Otherwise, clarify. Thank you.
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Vertigo	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-03-2021 12:30:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (pfe.liaukf)	Query 1: Closed	Response satisfies query

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1015**Subject No:** 10151134**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

Mar-03-2021 10:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-03-2021 10:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Casey Norton (pfe.cnorton)	Data Entry: NO End Date Time: Dec/21/2020 UNK:UNK	New Information
Mar-02-2021 04:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liao (pfe.liaukf)	Query 1: Opened	GPD CLIN: Please confirm if the subject's AE is still ongoing else provide end date as applicable.
Sep-18-2020 15:16:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	New Information
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Sep/1/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Sep-22-2020 15:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Sep-22-2020 12:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE Episode of Veritgo: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1015**Subject No:** 10151134**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

Sep-18-2020 14:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	site determined adverse event of vertigo was NOT serious
Sep-18-2020 09:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	ClinQuery For AE Vertigo [Vertigo]: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present and SAE form checked the 'Disability' box
Sep-18-2020 09:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	placed on incorrect SAE (incorrect SAE #)
Sep-18-2020 06:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Opened	SAE RECON:AER#2020326724 APPENDICITIS(onset date:17Aug2020)was reported as serious in Safety database but not serious in AE CRF. If this event is serious,update to yes.To downgrade the event in the Safety Database,please submit SAE form.
Sep-18-2020 06:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Vertigo: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	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
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Taylor Stannard	Data Entry: RELATED	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1015**Subject No:** 10151134**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

(US & Canada)

(pfe.tstannard)

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 10:26:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Nov-12-2020 10:05:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-12-2020 10:05:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: DRUG WITHDRAWN	New Information
Nov-11-2020 15:52:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Per EOT comment, it appears this event of Worsening Vertigo, contributed to the decision to cease treatment. If so, please consider updating this status to DRUG WITHDRAWN, and match to an EOT status of ADVERSE EVENT
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

Mar-03-2021 10:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-03-2021 10:37:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Casey Norton (pfe.cnorton)	Data Entry: RECOVERED/RESOLVED	New Information
Mar-03-2021 10:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Worsening and continuing episode of Veritgo: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-18-2020 15:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-18-2020 15:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RECOVERING/RESOLVING	New Information
Sep-18-2020 15:16:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Veritgo: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Date	Location	User	Value	Reason
Sep-11-2020 18:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-22-2020 15:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Data Entry:	AE downgraded from SAE
Sep-18-2020 06:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020361615	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1015**Subject No:** 10151134**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-11-2020 18:57:55 (UTC-05:00) Eastern 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
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Sep/1/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	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
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Date	Location	User	Value	Reason
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	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
Sep-11-2020 18:57:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1015**Subject No:** 10151134**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Nausea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Sep/1/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Date	Location	User	Value	Reason
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	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
Sep-11-2020 18:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1015**Subject No:** 10151134**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Diarrhea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Aug/28/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	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
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Date	Location	User	Value	Reason
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	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
Sep-11-2020 18:58:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Category:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Dec/22/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 13:54:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Chills	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Jan/13/2021 20:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Jan/15/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Date	Location	User	Value	Reason
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	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
Feb-12-2021 13:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1015**Subject No:** 10151134**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Jan/13/2021 20:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Jan/15/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Date	Location	User	Value	Reason
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	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
Feb-12-2021 13:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Jan/14/2021 03:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Jan/15/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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

Date	Location	User	Value	Reason
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	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
Feb-12-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS -
Audit Trail

Form Status:

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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Date	Location	User	Value	Reason
Nov-06-2020 15:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-06-2020 15:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-06-2020 15:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-06-2020 15:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Nov-06-2020 15:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Fluzone Quadrivalent	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Nov-06-2020 15:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/28/2020	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-08-2021 11:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Brent Spears (pfe.spearj09)	Query 1: Closed	Response satisfies query
Jan-06-2021 13:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-06-2021 13:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/14/2020	Transcription Error
Jan-05-2021 17:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Brent Spears (pfe.spearj09)	Query 1: Opened	Per source, initial contact completed 14Dec2020. Please reconcile.
Dec-21-2020 13:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/21/2020	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-24-2020 08:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	site confirms non-study access under EUA
Dec-23-2020 12:58:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Subject is eligible to receive vaccine. Discontinued treatment due to new/worsening vertigo which PI believed to be related to investigational product.
Dec-23-2020 11:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Subject discontinued treatment prior to vax 2 due to an AE. Please review and clarify the eligibility and/or the decision to continue for further vaccinations.
Dec-21-2020 13:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	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

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-21-2020 13:42:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Dec/21/2020	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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I. Consent Was:

Date	Location	User	Value	Reason
Dec-21-2020 13:42:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: OBTAINED Date Written Consent Obtained Dec/21/2020	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: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-21-2020 13:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-21-2020 13:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-21-2020 13:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (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:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151134**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 10:25:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 10:25:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-22-2020 10:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 10:25:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 10:25:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Dec/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 10:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSN5CN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 10:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BSN5CN	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

5.b

Date	Location	User	Value	Reason
Dec-22-2020 10:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSN5CW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 10:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BSN5CW	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-22-2020 10:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSN5CX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 10:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BSN5CX	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-22-2020 11:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BRFKMW	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 11:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BRFKMW	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (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:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151134**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 11:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 11:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-22-2020 11:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 11:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 11:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Dec/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 11:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BRFKMR	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 11:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BRFKMR	Initial Entry

Header Text: c4591001
Visit: V101_VAX3
Form Version: 10-Dec-2020 02:26
Site No: 1015
Subject No: 10151134
Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History
Form Status: Data Complete, Frozen, Verified
Site Name: (1015) Boston Medical Center
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:21

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-21-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-21-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-21-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-21-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/21/2020 13:20	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-21-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-21-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Dec-21-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Dec-21-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Dec-21-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-21-2020 13:43:33 (UTC-05:00) Eastern 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
Dec-21-2020 13:43:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151134

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-21-2020 13:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/14/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-21-2020 13:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-13-2021 13:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Jan/13/2021	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:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151134**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-21-2021 12:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-21-2021 12:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-21-2021 12:26:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 12:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-21-2021 12:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Jan/13/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-16-2021 16:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BR707N	Transcription Error
Jan-21-2021 12:26:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: MR707N	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Feb-16-2021 16:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BR707N	Transcription Error
Jan-21-2021 12:26:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: MR707N	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001
Visit: V102_VAX4
Form Version: 10-Dec-2020 02:26
Site No: 1015
Subject No: 10151134
Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History
Form Status: Data Complete, Frozen, Verified
Site Name: (1015) Boston Medical Center
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:21

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-13-2021 13:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-13-2021 13:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Jan/13/2021 12:45	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Jan-13-2021 13:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-13-2021 13:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-13-2021 13:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 13:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 09:46:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Steven Finelli (pfe.finels)	Query 1: Closed	data updated
Mar-10-2021 17:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Changed data per query
Mar-10-2021 15:29:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe.riddlj)	Query 1: Opened	DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of visit at visit 103.
Feb-12-2021 13:04:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Feb/10/2021	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151134

Generated By: pfe.levisse

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:21

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1. Contact Type:

Date	Location	User	Value	Reason
Feb-12-2021 13:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-12-2021 13:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Contact: Feb/10/2021	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:26**Form Status:** Data Complete, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151134**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**I. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-11-2021 16:53:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_30
Mar-11-2021 09:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Mar-11-2021 09:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry : Feb/1 0/202 1	Transcription Error
Mar-11-2021 00:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7668967;Status on the Disposition - Treatment form is COMPLETED at FURTHER_VACCINATION_EOT visit, but Date is different than Visit V103 Date. Please review and update as appropriate.
Mar-10-2021 17:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry : Mar/1 0/202 1	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-10-2021 17:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Mar-10-2021 17:34:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:21

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1. Subject Status

Date	Location	User	Value	Reason
Nov-12-2020 10:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	New Information
Nov-07-2020 14:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	New Information
Nov-06-2020 15:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-27-2020 16:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-27-2020 16:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-12-2020 10:04:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/6/2020	New Information
Nov-07-2020 14:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/6/2020	New Information
Nov-06-2020 15:23:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/6/2020	Initial Entry
Aug-27-2020 16:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/27/2020	Initial Entry
Aug-27-2020 16:37:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/27/2020	Initial Entry

090177e196ae3feb\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151134

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:21

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-06-2020 19:33:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Elizabeth Barnett (pfe.ebarnett)	Data Entry: Click Here to Enable	Initial Entry