

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/15/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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	[10151225]
2.	Birth Date:	(b) (6)/1995
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

Form: DATE OF VISIT

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

Date of Visit

1.	Date of Visit	Sep/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

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](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Sep/15/2020
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: 10151225

Generated By: pfe.levissc

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:	[Anxiety]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151225

Generated By: pfe.lewissc

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:	Sep/15/2020
2.	Weight:	[95.0]
3.	Unit:	LB
4.	Height:	[58.0]
5.	Unit:	in
6.	Body Mass Index:	[19.9]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[99.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1015

Subject No: 10151225

Generated By: pfe.levisc

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/15/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

Form: RANDOMIZATION

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](#)

Disposition

1.	Randomization Date :	Sep/15/2020
2.	Randomization Number:	[89727]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151225

Generated By: pfe.lewissc

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: Sep/15/2020
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	[BP9J3F]
5.b	Sample ID	[BLD0H2]
5.c	Sample ID	[BLD0H0]
5.d	Sample ID	[BLD0H1]

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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: Sep/15/2020
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	[BP9J3D]
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090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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:	Sep/15/2020 09:47
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: DATE OF VISIT

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

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/8/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1015

Subject No: 10151225

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/8/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9HLL]
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090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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:	Oct/8/2020 09:12
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: DATE OF VISIT

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

Date of Visit

1.	Date of Visit	Nov/5/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151225

Generated By: pfe.lewissc

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/5/2020
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	[BRFKG6]
5.b	Sample ID	[BSH173]
5.c	Sample ID	[BSH174]
5.d	Sample ID	[BSH175]

090177e196ae3fe7\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: 10151225

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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

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: 10151225 **Subject Initials:** ---

Generated By: pfe.levissc **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: 10151225

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_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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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: 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: 10151225

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: 10151225

Subject Initials: ---

Generated By: pfe.lewissc

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: 10151225

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/5/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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: 10151225

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 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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

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: 10151225

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	Dizziness	Oct/8/2020 20:00	NO End Date Time: Oct/12/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Injection site pain	Dec/23/2020 UNK:UNK	NO End Date Time: Dec/24/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	General muscle aches	Dec/23/2020 UNK:UNK	NO End Date Time: Dec/24/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Swollen neck lymph nodes - both sides	Dec/23/2020 UNK:UNK	NO End Date Time: Dec/24/2020 UNK:UNK	Repeating Pages
5.	ADVERSE EVENT	5	Fever 100.7	Dec/23/2020 UNK:UNK	NO End Date Time: Dec/24/2020 UNK:UNK	Repeating Pages
6.	ADVERSE EVENT	6	Fatigue	Jan/14/2021 13:00	NO End Date Time: Jan/16/2021 UNK:UNK	Repeating Pages
7.	ADVERSE EVENT	7	Headache	Jan/14/2021 13:00	NO End Date Time:	Repeating Pages

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Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
					Jan/16/2021 UNK:UNK	
8.	ADVERSE EVENT	8	Myalgia	Jan/14/2021 13:00	NO End Date Time: Jan/16/2021 UNK:UNK	Repeating Pages
9.	ADVERSE EVENT	9	Chills	Jan/14/2021 13:00	NO End Date Time: Jan/16/2021 UNK:UNK	Repeating Pages
10.	ADVERSE EVENT	10	Fever 101.0	Jan/14/2021 13:00	NO End Date Time: Jan/16/2021 UNK:UNK	Repeating Pages

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Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Dizziness]
4.	Start Date Time:	Oct/8/2020 20:00
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/12/2020 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

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Subject No: 10151225

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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Subject No: 10151225

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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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)	[Injection site pain]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/24/2020 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

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Subject No: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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Subject No: 10151225

Generated By: pfe.levisse

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Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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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)	[General muscle aches]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/24/2020 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

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Subject No: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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Subject Initials: ---

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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)	[Swollen neck lymph nodes - both sides]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/24/2020 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

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Subject No: 10151225

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Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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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)	[Fever 100.7]
4.	Start Date Time:	Dec/23/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/24/2020 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

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

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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)	[Fatigue]
4.	Start Date Time:	Jan/14/2021 13:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/16/2021 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

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Subject No: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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Form Status: Data Complete, Frozen, Verified

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)	[Headache]
4.	Start Date Time:	Jan/14/2021 13:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/16/2021 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

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Subject No: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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

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Subject No: 10151225

Generated By: pfe.levisse

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Form Status: Data Complete, Frozen, Verified

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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)	[Myalgia]
4.	Start Date Time:	Jan/14/2021 13:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/16/2021 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

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Subject No: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[9]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chills]
4.	Start Date Time:	Jan/14/2021 13:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/16/2021 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

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Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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

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Generated By: pfe.levisse

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[10]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fever 101.0]
4.	Start Date Time:	Jan/14/2021 13:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/16/2021 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

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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
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: 10151225

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

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Form Version: 17-Jul-2020 21:54

Site No: 1015

Subject No: 10151225

Generated By: pfe.levisse

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	[]

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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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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	Flucelvax	Oct/23/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

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

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).	[Flucelvax]
5.	Date:	Oct/23/2020

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3fe7\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: 10151225

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

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

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151225

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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?	

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.lewissc

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.lewissc

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

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: 10151225

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/17/2020
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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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
----	---	---

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

Form: DATE OF VISIT

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

Date of Visit

1.	Date of Visit	Dec/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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/22/2020
----	--------------	--

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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: 10151225

Generated By: pfe.lewissc

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/22/2020
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1015

Subject No: 10151225

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Dec/22/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3fe7\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: 10151225

Generated By: pfe.lewissc

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/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRFKNG]
5.b	Sample ID	[BSN5F0]
5.c	Sample ID	[BSN5DD]
5.d	Sample ID	[BSN5DF]

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRFKN4]
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090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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/22/2020 11:05
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

090177e196ae3fe7\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: 10151225

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/17/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

Withdrawal Of Consent

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

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: DATE OF VISIT

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

Date of Visit

1.	Date of Visit	Jan/14/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/14/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151225

Generated By: pfe.lewissc

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/14/2021
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	[BR707S]
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090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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:	Jan/14/2021 09:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: DATE OF VISIT

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

Date of Visit

1.	Date of Visit	Feb/17/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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/17/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

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	
Visit: V104_MONTH6	Form: CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	Form Status: Not Started
Site No: 1015	Site Name: (1015) Boston Medical Center
Subject No: 10151225	Subject Initials: ---
Generated By: pfe.levissc	Generated Time (GMT): 29-Mar-2021 04:21

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

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

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

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

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/17/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/5/2020

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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

[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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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 12:16:17 (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.

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1015

Subject No: 10151225

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	Sep-15-2020 12:20:28 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Dec-22-2020 13:52:21 (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: 10151225

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 12:16:17 (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-16-2021 16:45:49 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Elizabeth Barnett	Approved	Jan-22-2021 15:18:15 (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 12:27:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae3fe7\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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Elizabeth Barnett	Approved	Jan-21-2021 08:17:01 (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	Dec-22-2020 13:51:40 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Elizabeth Barnett	Approved	Nov-06-2020 19:44:06 (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.

090177e196ae3fe7\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: 10151225

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
Sep-15-2020 12:19:56 (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
Sep-15-2020 12:19:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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
Sep-15-2020 12:20:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: OBTAINED Date Written Consent Obtained Sep/15/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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
Sep-15-2020 12:19:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10151225	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: (b) (6)/1995	Transcription Error
Sep-15-2020 12:19:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1995	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-15-2020 12:20:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-15-2020 12:20:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 12:20:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: WHITE	Initial Entry

090177e196ae3fe7\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: 10151225

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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1. Date of Visit

Date	Location	User	Value	Reason
Sep-15-2020 12:20:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/15/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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
Sep-15-2020 12:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-15-2020 12:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-15-2020 12:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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

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1.a

Date	Location	User	Value	Reason
Sep-15-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T Anxiety ern: Start Date: UNK/UNK/2 013 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-15-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Anxiety	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: UNK/UNK/2013	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-15-2020 12:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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
Sep-15-2020 12:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/15/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 95.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 58.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:45 (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
Sep-15-2020 12:21:45 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19.9	Initial Entry

090177e196ae3fe7\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: 10151225

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

Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Sep-15-2020 12:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Record Identifier 1 : Temperature: 99.1 Temperature Uni F t: Temperature Loc ORAL CAV ation:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:45 (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
Sep-15-2020 12:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 99.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:45 (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
Sep-15-2020 12:21:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sep/15/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-15-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-15-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Choriogonadotropin Beta_PX11 3	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-15-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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
Sep-15-2020 12:28:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/15/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-15-2020 12:28:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 89727	Initial Entry

090177e196ae3fe7\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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 13:00:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-17-2020 13:00:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-17-2020 13:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 13:00:28 (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.
Sep-17-2020 13:00:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 13:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BP9J3F	Initial Entry

090177e196ae3fe7\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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 13:00:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BP9J3F	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-17-2020 13:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BLD0H2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 13:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BLD0H2	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-17-2020 13:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BLD0H0	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 13:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BLD0H0	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-17-2020 13:01:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BLD0H1	Initial Entry

090177e196ae3fe7\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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 13:01:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BLD0H1	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1015**Subject No:** 10151225**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-17-2020 13:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-17-2020 13:02:05 (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
Sep-17-2020 13:02:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 13:02:05 (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.
Sep-17-2020 13:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 13:02:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BP9J3D	Initial Entry

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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 13:02:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BP9J3D	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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-15-2020 12:28:31 (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
Sep-15-2020 12:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-15-2020 12:28:31 (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
Sep-15-2020 12:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/15/2020 09:47	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-15-2020 12:28:31 (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
Sep-15-2020 12:28:31 (UTC-05:00) Eastern	ACV0PFEINFP6000	Taylor Stannard	Data Entry: RIGHT	Initial Entry

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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

Time (US & Canada)		(pfe.tstannard)	
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7. Route:

Date	Location	User	Value	Reason
Sep-15-2020 12:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-15-2020 12:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-15-2020 12:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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
Sep-15-2020 12:29:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO - REACTOGENICITY E-DI ARY 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: 10151225

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
Oct-16-2020 01:57:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Closed	Closed as data updated.
Oct-15-2020 14:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Changed data per query
Oct-09-2020 08:15:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: Kindly review and complete 'Nasal Swab form' at this visit. Thank you.
Oct-08-2020 13:03:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Oct/8/2020	Initial Entry

090177e196ae3fe7\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: 10151225

Generated By: pfe.lewissc

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
Oct-08-2020 13:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Oct/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-08-2020 13:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Record Identifier 1 :: Temperature: 98.7 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-08-2020 13:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-08-2020 13:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 98.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-08-2020 13:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: F	Initial Entry

090177e196ae3fe7\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: 10151225

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-08-2020 13:03:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-08-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-08-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-08-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Oct/8/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-08-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-08-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-08-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-08-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-08-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Choriogonadotropin Beta_PX11 3	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-08-2020 13:04:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fe7\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:** 10151225**Generated By:** pfe.levissc**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-15-2020 14:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 14:34:19 (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
Oct-15-2020 14:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 14:34:19 (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.
Oct-15-2020 14:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 14:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BP9HLL	Initial Entry

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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 14:34:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BP9HLL	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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
Oct-08-2020 13:05:25 (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
Oct-08-2020 13:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-08-2020 13:05:25 (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
Oct-08-2020 13:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Oct/8/2020 09:12	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-08-2020 13:05:25 (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
Oct-08-2020 13:05:25 (UTC-05:00) Eastern	ACV0PFEINFP6000	Taylor Stannard	Data Entry: RIGHT	Initial Entry

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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

Time (US & Canada)		(pfe.tstannard)	
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7. Route:

Date	Location	User	Value	Reason
Oct-08-2020 13:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-08-2020 13:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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
Oct-08-2020 13:05:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

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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1. Date of Visit

Date	Location	User	Value	Reason
Nov-05-2020 14:45:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Nov/5/2020	Initial Entry

090177e196ae3fe7\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:** 10151225**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-06-2020 14:40:27 (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-06-2020 14:40:27 (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-06-2020 14:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-06-2020 14:40:27 (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.
Nov-06-2020 14:40:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Nov/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-06-2020 14:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BRFKG6	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 14:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BRFKG6	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-06-2020 14:42:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSH173	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 14:42:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BSH173	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-06-2020 14:42:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSH174	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 14:42:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BSH174	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-06-2020 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSH175	Initial Entry

090177e196ae3fe7\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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 14:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BSH175	Initial Entry

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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-05-2020 14:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Nov/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-05-2020 14:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-05-2020 14:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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
Nov-05-2020 14:46:53 (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: 10151225

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-20-2021 17:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

090177e196ae3fe7\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: 10151225

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-20-2021 17:26:11 (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: 10151225

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-20-2021 17:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

090177e196ae3fe7\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: 10151225

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-20-2021 17:27:20 (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: 10151225

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-24-2021 12:48:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

090177e196ae3fe7\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: 10151225

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-24-2021 12:49:13 (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: 10151225

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-24-2021 13:10:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

090177e196ae3fe7\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: 10151225

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-24-2021 13:10:51 (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: 10151225

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-24-2021 13:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

090177e196ae3fe7\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: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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. Category:

Date	Location	User	Value	Reason
Nov-05-2020 14:46:53 (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
Nov-05-2020 14:46:53 (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
Nov-05-2020 14:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dizziness	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-05-2020 14:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Oct/8/2020 20:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-05-2020 14:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Oct/12/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3fe7\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: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Nov-05-2020 14:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-05-2020 14:46:53 (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
Nov-05-2020 14:46:53 (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
Nov-05-2020 14:46:53 (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
Nov-05-2020 14:46:53 (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
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-05-2020 14:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-05-2020 14:46:53 (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
Nov-05-2020 14:46:53 (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
Nov-05-2020 14:46:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Jan-20-2021 17:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-20-2021 17:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-20-2021 17:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-20-2021 17:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Dec/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 17:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO End Date Time: Dec/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3fe7\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: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Jan-20-2021 17:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry
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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
Jan-20-2021 17:25:46 (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-20-2021 17:25:46 (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-20-2021 17:25:46 (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-20-2021 17:25:46 (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
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-20-2021 17:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-20-2021 17:25:46 (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
Jan-20-2021 17:25:46 (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-20-2021 17:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Jan-20-2021 17:26:11 (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-20-2021 17:26:11 (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
Jan-20-2021 17:26:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: General muscle aches	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-20-2021 17:26:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 17:26:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Dec/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-20-2021 17:26:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry
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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
Jan-20-2021 17:26:11 (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-20-2021 17:26:11 (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-20-2021 17:26:11 (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-20-2021 17:26:11 (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
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-20-2021 17:26:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-20-2021 17:26:11 (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
Jan-20-2021 17:26:11 (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-20-2021 17:26:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Jan-20-2021 17:26:39 (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-20-2021 17:26:39 (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
Jan-21-2021 13:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 1: Closed	Response satisfies query
Jan-21-2021 13:17:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-21-2021 13:17:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Swollen neck lymph nodes - bot h sides	Transcription Error
Jan-21-2021 12:31:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (pfe.tonkovs)	Query 1: Opened	GPD Clin: Please can you update the verbatim term to include swollen neck lymph nodes location - right or left side? Thanks
Jan-20-2021 17:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Swollen neck lymph nodes	Initial Entry

4. Start Date Time:

090177e196ae3fe7\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: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Date	Location	User	Value	Reason
Jan-20-2021 17:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Dec/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 17:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO End Date Time: Dec/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-20-2021 17:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-20-2021 17:26:39 (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
Jan-20-2021 17:26:39 (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:

090177e196ae3fe7\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: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Date	Location	User	Value	Reason
Jan-20-2021 17:26:39 (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
Jan-20-2021 17:26:39 (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
Jan-20-2021 17:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-20-2021 17:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 17:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-20-2021 17:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Jan-20-2021 17:27:20 (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-20-2021 17:27:20 (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-20-2021 17:27:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Fever 100.7	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-20-2021 17:27:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/23/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-20-2021 17:27:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Dec/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3fe7\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: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Jan-20-2021 17:27:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry
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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
Jan-20-2021 17:27:20 (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-20-2021 17:27:20 (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-20-2021 17:27:20 (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-20-2021 17:27:20 (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
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-20-2021 17:27:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-20-2021 17:27:20 (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
Jan-20-2021 17:27:20 (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-20-2021 17:27:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Feb-24-2021 12:48:44 (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-24-2021 12:48:44 (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-24-2021 12:48:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-24-2021 12:48:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Jan/14/2021 13:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 12:48:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Jan/16/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Feb-24-2021 12:48:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-24-2021 12:48:44 (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-24-2021 12:48:44 (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-24-2021 12:48:44 (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-24-2021 12:48:44 (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
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Feb-24-2021 12:48:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-24-2021 12:48:44 (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
Feb-24-2021 12:48:44 (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-24-2021 12:48:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Feb-24-2021 12:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-24-2021 12:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-24-2021 12:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-24-2021 12:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Jan/14/2021 13:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 12:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO End Date Time: Jan/16/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3fe7\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:** 10151225**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - 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

Mar-03-2021 13:20:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Brent Spears (pfe.spearj09)	Query 1: Closed	Response satisfies query
Mar-03-2021 11:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-03-2021 11:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Casey Norton (pfe.cnorton)	Data Entry: 2	Changed Information
Mar-02-2021 09:06:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marjo Virtanen (pfe.virtam)	Query 1: Opened	Please check toxicity grade and reconcile eCRF.
Feb-24-2021 12:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 12:49:13 (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-24-2021 12:49:13 (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-24-2021 12:49:13	ACV0PFEINFP6000	Taylor	Data Entry:	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		Stannard (pfe.tstannard)	RELATED	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-24-2021 12:49:13 (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-24-2021 12:49:13 (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-24-2021 12:49:13 (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
Feb-24-2021 12:49:13 (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-24-2021 12:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category:

Date	Location	User	Value	Reason
Feb-24-2021 13:10:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-24-2021 13:10:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 8	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-24-2021 13:10:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Myalgia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-24-2021 13:10:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Jan/14/2021 13:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 13:10:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO End Date Time: Jan/16/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3fe7\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:** 10151225**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - 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

Mar-03-2021 13:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Brent Spears (pfe.spearj09)	Query 1: Closed	Response satisfies query
Mar-03-2021 11:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-03-2021 11:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Casey Norton (pfe.cnorton)	Data Entry: 2	Changed Information
Mar-02-2021 09:06:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marjo Virtanen (pfe.virtam)	Query 1: Opened	Please check toxicity grade and reconcile eCRF.
Feb-24-2021 13:10:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 13:10:27 (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-24-2021 13:10:27 (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-24-2021 13:10:27	ACV0PFEINFP6000	Taylor	Data Entry:	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		Stannard (pfe.tstannard)	RELATED	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-24-2021 13:10:27 (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-24-2021 13:10:27 (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-24-2021 13:10:27 (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
Feb-24-2021 13:10:27 (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-24-2021 13:10:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Feb-24-2021 13:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-24-2021 13:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 9	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-24-2021 13:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Chills	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-24-2021 13:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Jan/14/2021 13:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 13:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO End Date Time: Jan/16/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3fe7\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: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Feb-24-2021 13:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-24-2021 13:10:51 (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-24-2021 13:10:51 (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-24-2021 13:10:51 (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-24-2021 13:10:51 (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
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Feb-24-2021 13:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-24-2021 13:10:51 (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
Feb-24-2021 13:10:51 (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-24-2021 13:10:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Feb-24-2021 13:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-24-2021 13:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 10	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-24-2021 13:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Fever 101.0	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-24-2021 13:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Jan/14/2021 13:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 13:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO End Date Time: Jan/16/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3fe7\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: 10151225

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Feb-24-2021 13:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-24-2021 13:11:18 (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-24-2021 13:11:18 (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-24-2021 13:11:18 (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-24-2021 13:11:18 (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
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Feb-24-2021 13:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-24-2021 13:11:18 (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
Feb-24-2021 13:11:18 (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-24-2021 13:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Nov-05-2020 14:50:05 (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: 10151225

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-05-2020 14:50:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-05-2020 14:50:05 (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-05-2020 14:50:05 (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-05-2020 14:50:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Flucelvax	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Nov-05-2020 14:50:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Oct/23/2020	Initial Entry

090177e196ae3fe7\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: 10151225

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
Dec-22-2020 13:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/17/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - 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. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Dec-22-2020 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Participant is willing to return fo r Vaccination 3 Participant is: eligible per local/national rec ommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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-22-2020 13:52:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/22/2020	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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Dec-22-2020 13:52:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Dec/22/2020	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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-22-2020 13:52:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-22-2020 13:52:32 (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-22-2020 13:52:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Dec-22-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Dec-22-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-22-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Dec/22/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Dec-22-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Dec-22-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Dec-22-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-22-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Dec-22-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Choriogonadotropin Beta_PX11 3	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Dec-22-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fe7\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:** 10151225**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-04-2021 15:06:14 (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-04-2021 15:06:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-04-2021 15:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-04-2021 15:06:14 (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-04-2021 15:06:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Dec/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-04-2021 15:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BRFKNG	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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 15:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BRFKNG	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-04-2021 15:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BSN5F0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 15:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BSN5F0	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-05-2021 09:57:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BSN5DD	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 09:57:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BSN5DD	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-05-2021 09:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BSN5DF	Initial Entry

090177e196ae3fe7\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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 09:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BSN5DF	Initial Entry

090177e196ae3fe7\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:** 10151225**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-04-2021 14:49:51 (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-04-2021 14:49:51 (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-04-2021 14:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-04-2021 14:49:51 (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-04-2021 14:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Dec/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-04-2021 14:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BRFKN4	Initial Entry

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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 14:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BRFKN4	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1015

Subject No: 10151225

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-22-2020 13:53:12 (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-22-2020 13:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-22-2020 13:53:12 (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-22-2020 13:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/22/2020 11:05	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-22-2020 13:53:12 (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-22-2020 13:53:12 (UTC-05:00) Eastern	ACV0PFEINFP6000	Taylor Stannard	Data Entry: LEFT	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

Time (US & Canada)		(pfe.tstannard)	
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7. Route:

Date	Location	User	Value	Reason
Dec-22-2020 13:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Dec-22-2020 13:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Dec-22-2020 13:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-22-2020 13:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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-22-2020 13:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-22-2020 13:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/17/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-22-2020 13:51:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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-22-2021 01:43:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Jan-21-2021 12:28:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Changed data per query
Jan-21-2021 08:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: Kindly review and complete 'Nasal Swab' form at this visit. Thank you.
Jan-20-2021 17:23:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Jan/14/2021	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Jan/14/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-20-2021 17:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-20-2021 17:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Choriogonadotropin Beta_PX11 3	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001**Visit:** V102_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151225**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-21-2021 12:27:51 (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 12:27:51 (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 12:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 12:27:51 (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 12:27:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Jan/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-16-2021 16:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BR707S	Transcription Error

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: 10151225

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-21-2021 12:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: MR707S	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 16:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BR707S	Transcription Error
Jan-21-2021 12:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: MR707S	Initial Entry

090177e196ae3fe7\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: 10151225

Generated By: pfe.levissc

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-20-2021 17:24:22 (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-20-2021 17:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:22 (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-20-2021 17:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Jan/14/2021 09:40	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:22 (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-20-2021 17:24:22 (UTC-05:00) Eastern	ACV0PFEINFP6000	Taylor Stannard	Data Entry: RIGHT	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

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: 10151225

Subject Initials: ---

Generated By: pfe.levissc

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

Time (US & Canada)		(pfe.tstannard)	
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7. Route:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-20-2021 17:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-20-2021 17:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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-20-2021 17:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3fe7\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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
Feb-24-2021 12:34:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Feb/17/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

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-24-2021 12:34:57 (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-24-2021 12:34:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Contact: Feb/17/2021	Initial Entry

090177e196ae3fe7\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, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151225**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-26-2021 01:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sanjay Mishra (pfe.mishrs01)	Query 1: Clo sed	Dates are matching.
Feb-25-2021 06:45:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7450748;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-24-2021 13:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry : Feb/1 7/202 1	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-24-2021 13:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-24-2021 13:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151225

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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1. Subject Status

Date	Location	User	Value	Reason
Nov-05-2020 14:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-15-2020 12:28:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-15-2020 12:20:45 (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-05-2020 14:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/5/2020	Initial Entry
Sep-15-2020 12:28:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry
Sep-15-2020 12:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry

090177e196ae3fe7\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: 10151225

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 19:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Elizabeth Barnett (pfe.ebarnett)	Data Entry: Click Here to Enable	Initial Entry