

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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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: 10151035

Generated By: pfe.lewissc

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 Aug/16/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10151035]
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:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151035

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	Aug/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151035

Generated By: pfe.lewissc

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	Aug/16/2020
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: 10151035

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

Form Comments

Medical History Details

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

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/16/2020
2.	Weight:	[138.0]
3.	Unit:	LB
4.	Height:	[65.0]
5.	Unit:	in
6.	Body Mass Index:	[23.0]

Vital Signs Details

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1015

Subject No: 10151035

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:	Aug/16/2020
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:	

090177e196ae3fea\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: 10151035

Generated By: pfe.lewissc

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 :	Aug/16/2020
2.	Randomization Number:	[51423]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/16/2020
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	[BLD02H]
5.b	Sample ID	[BLD02J]
5.c	Sample ID	[BM8FBH]
5.d	Sample ID	[BM8FBF]
5.e	Sample ID	[BM8FBG]

090177e196ae3fea\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: 10151035

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/16/2020
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	[BM8FBB]
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090177e196ae3fea\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: 10151035

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/16/2020 12:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fea\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: 10151035

Generated By: pfe.levisc

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	YES - REACTOGENICITY E-DIARY 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: 10151035

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/4/2020
2.	Erroneous Visit	

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151035

Generated By: pfe.lewissc

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:	Sep/4/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1015

Subject No: 10151035

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/4/2020
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:	

090177e196ae3fea\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: 10151035

Generated By: pfe.lewissc

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/4/2020
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	[BP9HXV]
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090177e196ae3fea\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: 10151035

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/4/2020 15:54
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fea\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: 10151035

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/2/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

eCRF Audit Trail History

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BLD0L1]
5.b	Sample ID	[BP9HK8]
5.c	Sample ID	[BLD0L3]

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151035

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	Mar/1/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151035

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: Mar/1/2021
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	[BSH1J1]
5.b	Sample ID	[BSH1J2]
5.c	Sample ID	[BSH1J3]
5.d	Sample ID	[BR70G3]

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151035

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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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090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151035

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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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090177e196ae3fea\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: 10151035

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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae3fea\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: 10151035

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

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: 10151035

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

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: 10151035

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: 10151035 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:21

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

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: 10151035

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/06/2020

Form: DATE OF VISIT

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: 10151035

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	Sep/6/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/06/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/06/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levissc

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: Sep/6/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Patient called reporting symptoms reported in eDiary, wanted to know if she may take pain medication. Advised to take pain medication. Agreed to contact with any other issues or concerns.]

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: 10151035

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1015

Subject No: 10151035

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

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:	
----	-----------------------	--

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

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: 10151035

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

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: 10151035

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	Swollen lymph node - left armpit axillary	Sep/4/2020 17:00	NO End Date Time: Sep/8/2020 UNK:UNK	Repeating Pages

090177e196ae3fea\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: 10151035

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Swollen lymph node - left armpit axillary]
4.	Start Date Time:	Sep/4/2020 17:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/8/2020 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

090177e196ae3fea\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: 10151035

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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	[]

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

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: 10151035

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

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1015

Subject No: 10151035

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

[Back to Form](#)

Medication Error

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

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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.	Date:	//

090177e196ae3fea\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: 10151035

Subject Initials: ---

Generated By: pfe.lewissc

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: 10151035

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[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?	

090177e196ae3fea\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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151035

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: 10151035

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	Form: TRANSFUSIONS
Visit: Logs - Unscheduled	Form Status: Not Started
Form Version: 22-Apr-2020 21:03	Site Name: (1015) Boston Medical Center
Site No: 1015	Subject Initials: ---
Subject No: 10151035	Generated Time (GMT): 29-Mar-2021 04:21
Generated By: pfe.levisse	

[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: 10151035

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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Vital Signs

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

Vital Signs Details

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

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

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:	

090177e196ae3fea\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: 10151035

Subject Initials: ---

Generated By: pfe.levisc

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?	

090177e196ae3fea\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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

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: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.lewissc

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

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

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: 10151035

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/15/2020
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: 10151035

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 and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151035

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/15/2020
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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Death Details

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

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Subject Status

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

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151035

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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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: 10151035

Subject Initials: ---

Generated By: pfe.levissc

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Elizabeth Barnett	Approved	Mar-11-2021 10:21:10 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1015

Subject No: 10151035

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-17-2020 12:41:47 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-17-2020 12:42:12 (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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Elizabeth Barnett	Approved	Mar-11-2021 10:21:10 (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	Mar-03-2021 11:50:27 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Elizabeth Barnett	Approved	Jan-21-2021 19:46:55 (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-23-2020 13:15:05 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae3fea\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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Elizabeth Barnett	Approved	Oct-26-2020 13:37:45 (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	Oct-22-2020 14:52:35 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Elizabeth Barnett	Approved	Oct-22-2020 06:10:45 (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.

090177e196ae3fea\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: 10151035

Generated By: pfe.lewissc

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-17-2020 12:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 12:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151035

Generated By: pfe.lewissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-17-2020 12:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: OBTAINED Date Written Consent Obtained Aug/16/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-17-2020 12:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10151035	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:41:00 (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
Aug-17-2020 12:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-17-2020 12:41:31 (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
Aug-17-2020 12:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: WHITE	Initial Entry

090177e196ae3fea\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: 10151035

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
Aug-17-2020 12:41:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Aug/16/2020	Initial Entry

090177e196ae3fea\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: 10151035

Generated By: pfe.lewissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-17-2020 12:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 30-Jul-2020 21:28**Site No:** 1015**Subject No:** 10151035**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[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Aug-17-2020 12:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/16/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 138.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 65.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23.0	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 30-Jul-2020 21:28**Site No:** 1015**Subject No:** 10151035**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)

7.a

Date	Location	User	Value	Reason
Aug-17-2020 12:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Record Identifier 1 :: Temperature: 97.9 Temperature Unit F : Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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. Lab Panel:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/16/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-17-2020 12:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-17-2020 12:42:51 (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
Aug-17-2020 12:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-17-2020 12:42:51 (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
Aug-17-2020 12:42:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fea\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: 10151035

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
Aug-17-2020 12:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Aug/16/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-17-2020 12:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> 51423	Initial Entry

090177e196ae3fea\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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-17-2020 16:30:35 (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
Aug-17-2020 16:30:35 (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-07-2020 04:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 3: Closed	Response satisfies query
Sep-06-2020 19:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Sep-06-2020 19:34:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> YES Date of Collection: Aug/16/2020	Transcription Error
Sep-05-2020 22:11:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 3: Opened	Sample collected on 17AUG2020 which is after Vaccination date of 16Aug2020. Please Verify the dates and update as appropriate. Else specify in the item "If no sample was collected or sample was not collected"

090177e196ae3fea\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:** 10151035**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21

				according to protocol, please provide".
Sep-02-2020 08:32:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 2: Closed	Response satisfies query
Sep-01-2020 10:25:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 2: Answered	Changed data per query
Sep-01-2020 08:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 2: Opened	DM: Barcode BM8FHB was received by the lab but missing in inform. Please review and update appropriately or submit a SCF.
Aug-17-2020 16:30:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 16:30:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-17-2020 16:30:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 16:30:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BLD02H	Initial Entry

5.a Sample ID

090177e196ae3fea\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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-18-2020 01:33:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Aug-17-2020 20:17:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Original value is correct
Aug-17-2020 19:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4228507;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Aug-17-2020 16:30:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry : BLD0 2H	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-17-2020 20:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BLD02J	Transcription Error
Aug-17-2020 16:30:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BLD02H	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 01:33:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Aug-17-2020 20:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-17-2020 20:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry</u> : BLD02J	Transcription Error
Aug-17-2020 19:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4228508;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Aug-17-2020 16:30:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry</u> : BLD02H	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 13:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry</u> : Sample ID: BM8FBH	Transcription Error

090177e196ae3fea\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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-01-2020 10:25:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8FHB	Transcription Error
Aug-28-2020 12:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8FBH	Transcription Error
Aug-17-2020 20:16:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8FHB	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151035**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 08:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 3: Closed	error
Oct-21-2020 06:03:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ankita Thakur (pfe.thakua20)	Query 3: Reissued:Opened	DM: Thank you for the response, at Visit 1, now the form is unfrozen, hence please update the data appropriate as per the below query. Else clarify.
Oct-20-2020 10:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 3: Answered	Please unfreeze so I may update, thanks!
Oct-20-2020 08:15:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 3: Opened	LIMS Query: As per lab, sample ID is BM8FHB and not BM8FBH as reported here. Please check and correct the data, else clarify.
Sep-04-2020 04:43:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 2: Closed	Response satisfies query
Sep-03-2020 13:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Sep-03-2020 13:37:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8FBH	Transcription Error
Sep-03-2020 11:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 2: Opened	DM: Lab received BM8FBH. Please confirm barcode and update accordingly or submit SCF.

090177e196ae3fea\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: 10151035
Generated By: pfe.levisse
Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1015) Boston Medical Center
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:21

Sep-01-2020 10:25:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8FHB	Transcription Error
Aug-28-2020 13:52:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Closed	Response satisfies query
Aug-28-2020 12:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-28-2020 12:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8FBH	Transcription Error
Aug-28-2020 10:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Opened	DM: BM8FHB entered instead of BM8FBH. Please confirm barcode and update accordingly or clarify.
Aug-17-2020 20:16:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8FHB	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-28-2020 16:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8FBF	Transcription Error
Aug-28-2020 16:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8FF5	Transcription Error
Aug-18-2020 10:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8FBF	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 16:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BM8FBF	Transcription Error
Aug-28-2020 16:06:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BM8FF5	Transcription Error
Aug-18-2020 10:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BM8FBF	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-18-2020 10:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BM8FBG	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 10:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BM8FBG	Initial Entry

090177e196ae3fea\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:** 10151035**Generated By:** pfe.levisse**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
Aug-17-2020 13:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 13:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-17-2020 13:15:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 13:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-17-2020 13:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Aug/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 13:15:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8FBB	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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 13:15:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BM8FBB	Initial Entry

090177e196ae3fea\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: 10151035

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-17-2020 12:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-17-2020 12:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-17-2020 12:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-17-2020 12:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/16/2020 12:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-17-2020 12:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-17-2020 12:43:35 (UTC-05:00) Eastern	ACV0PFEINFP6000	Taylor Stannard	Data Entry: LEFT	Initial Entry

090177e196ae3fea\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: 10151035

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
Aug-17-2020 12:43:35 (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
Aug-17-2020 12:43:35 (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
Aug-17-2020 12:43:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

090177e196ae3fea\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: 10151035

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
Aug-17-2020 12:43:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES - REACTOGENICITY E-D IARY 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: 10151035

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Sep-07-2020 05:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Sep-06-2020 19:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Changed data per query
Sep-05-2020 22:12:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	Please complete "Electronic sample tracking-NASAL SWAB" CRF.
Sep-04-2020 15:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/4/2020	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151035**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the las O t day the Subject Diary w as completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Symptom:: FA TI	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

					GU E NO Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:
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2.b Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic s ymptoms present on the l ast day the Subject Diary was completed?:	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic s ymptoms present on the l ast day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Symptom:: DIA RR HE A Were fever or systemic s ymptoms present on the l ast day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Symptom:: NEW OR WORSE NED MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

2.h

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Symptom:: NEW O R WORS ENED J OINT PA IN Were fever or syste mic symptoms prese nt on the last day th e Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NEW OR WORSE NED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: LEFT	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary was completed?:	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-04-2020 15:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151035

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
Sep-04-2020 15:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/4/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-04-2020 15:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Record Identifier 1 :: Temperature: 97.9 Temperature Unit F : Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:37 (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
Sep-04-2020 15:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 97.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: F	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151035

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
Sep-04-2020 15:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

090177e196ae3fea\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-04-2020 15:53:49 (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-04-2020 15:53:49 (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-04-2020 15:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sep/4/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-04-2020 15:53:49 (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-04-2020 15:53:49 (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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090177e196ae3fea\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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Sep-04-2020 15:53:49 (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-04-2020 15:53:49 (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-04-2020 15:53:49 (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-04-2020 15:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NEGATIVE	Initial Entry

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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: 10151035

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-06-2020 19:34:02 (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-06-2020 19:34:02 (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-06-2020 19:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-06-2020 19:34:02 (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-06-2020 19:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Sep/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-06-2020 19:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BP9HXV	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-06-2020 19:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BP9HXV	Initial Entry

090177e196ae3fea\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:** 10151035**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[Back to Form](#)**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-04-2020 15:54:48 (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-04-2020 15:54:48 (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-04-2020 15:54:48 (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-10-2020 08:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Clos ed	Response satisfies query
Sep-09-2020 11:30:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Ans wered	Changed data per query
Sep-07-2020 03:25:30 (UTC-05:00) Eastern Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Ope ned	PDQ: Subject has reported with Severe symptoms/reactions

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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(US & Canada)				on '2020-09-05'. Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate. "[malipn01 SDQ=4039]"
Sep-04-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/4/2020 15:54	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-04-2020 15:54:48 (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-04-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-04-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-04-2020 15:54:48 (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-04-2020 15:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

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
Oct-23-2020 03:53:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Minal Pathak (pfe.patham13)	Query 2: Closed	Response satisfies query
Oct-22-2020 14:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 2: Answered	Changed data per query
Oct-22-2020 10:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 2: Opened	DM1: Thank you for response. Please review if data is available and provide details on 'Immunogenicity form' at this visit.
Oct-21-2020 01:01:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Closed	Closed as query kept in candidate state.
Oct-21-2020 01:00:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 2: Candidate	DM1: Thank you for response. Please review if data is available and provide details on 'Immunogenicity form' at this visit.
Oct-16-2020 01:02:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Reissued:Opened	DM1: Thank you for response. Please keep this query open at your end. Once data is available and updated, respond to the query.
Oct-15-2020 14:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Hello, we are currently trying to find the barcodes for this participant. Will update as soon as the lab staff can get it to

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

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

				us.
Oct-09-2020 10:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: Kindly review and complete 'Immunogenicity form' at this visit. Thank you.
Oct-02-2020 15:37:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Oct/2/2020	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L
Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
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Form Status: Data Complete, Locked, Frozen, Verified
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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Symptom:: FA TI	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1015 **Site Name:** (1015) Boston Medical Center
Subject No: 10151035 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:21

			GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151035**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**2.c Symptom:**

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

2.e

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic s ymptoms present on the l ast day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Symptom:: DIA RR HE A Were fever or systemic s ymptoms present on the l ast day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Symptom:: NEW OR WORSE NED MUSCLE PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

2.h

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Symptom:: NEW O R WORS ENED J OINT PA IN Were fever or syste mic symptoms prese nt on the last day th e Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: LEFT	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Injection Site Reaction:: RE DN ESS Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary was completed?:	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L
Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1015
Site Name: (1015) Boston Medical Center
Subject No: 10151035
Subject Initials: ---
Generated By: pfe.levisse
Generated Time (GMT): 29-Mar-2021 04:21

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-02-2020 15:37:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 14:52:35 (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-22-2020 14:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-22-2020 14:52:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 14:52:35 (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-22-2020 14:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Oct/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 14:52:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BLD0L1	Initial Entry

090177e196ae3fea\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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 14:52:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BLD0L1	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-22-2020 14:54:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BP9HK8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 14:54:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BP9HK8	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-22-2020 14:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BLD0L3	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 14:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BLD0L3	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151035

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
Mar-03-2021 11:50:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Mar/1/2021	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001**Visit:** V4_MONTH6_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1015**Subject No:** 10151035**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-03-2021 11:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-03-2021 11:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 11:50:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 11:50:37 (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.
Mar-03-2021 11:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Mar/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 11:50:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSH1J1	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 11:50:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BSH1J1	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-03-2021 11:51:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BSH1J2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 11:51:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BSH1J2	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-03-2021 11:52:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BSH1J3	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 11:52:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BSH1J3	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-03-2021 11:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sample ID: BR70G3	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 11:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> BR70G3	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/06/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-09-2020 11:29:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Sep/6/2020	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/06/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

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I. Assessments

Date	Location	User	Value	Reason
Sep-09-2020 11:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 11:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Sep-09-2020 11:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/06/2020

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151035

Generated By: pfe.levissc

Form: CONTACT OUTCOME - UNPLANNED - 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. Contact Type:

Date	Location	User	Value	Reason
Sep-09-2020 11:30:34 (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
Sep-09-2020 11:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Contact: Sep/6/2020 Contact Outcome: VISIT NOT REQUIRED, IN VESTIGATOR DECISION	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Sep-12-2020 05:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Premraj Bhoyar (pfe.bhoyap)	Query 1: Closed	Data updated by site.
Sep-11-2020 13:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-11-2020 13:14:29 (UTC-05:00)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Patient cal	New Information

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Sep/06/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1015**Subject No:** 10151035**Generated By:** pfe.levisse**Form:** CONTACT OUTCOME - UNPLANNED - 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

Eastern Time (US & Canada)			led reporting symptoms reported in eDiary, wanted to know if she may take pain medication. Advised to take pain medication. Agreed to contact with any other issues or concerns.	
Sep-10-2020 17:35:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	The following text was indicated in the comment field [fever,muscle soreness]. For any symptoms, AEs, or other key data should be collected on the appropriate page or eDiary. Please review and update as necessary. "[nazairl SDQ=5843]"
Sep-09-2020 11:30:34 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Patient called reported	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/06/2020

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: CONTACT OUTCOME - UNPLANNED - 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

(US & Canada)			ng low-grade fever and muscle soreness, wanted to know if she may take pain medication. Advised to take pain medication. Agreed to contact with any other issues or concerns.	
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090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

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
Oct-05-2020 10:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Oct/2/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-05-2020 10:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-05-2020 10:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fea\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: 10151035

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
Oct-02-2020 15:39:51 (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: 10151035

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Oct-02-2020 15:39:51 (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
Oct-02-2020 15:39:51 (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
Oct-21-2020 20:43:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Closed	Response satisfies query
Oct-20-2020 10:37:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-20-2020 10:37:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Swollen lymph node - left armpit t axillary	New Information
Oct-20-2020 01:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	ClinQuery: Swollen lymph node – armpit: please specify location re axillary and whether bilateral, left, or right
Oct-19-2020 21:36:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Candidate	ClinQuery: Swollen lymph node – armpit: please specify location re axillary and whether bilateral,

090177e196ae3fea\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:** 10151035**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

				left, or right
Oct-02-2020 15:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Swollen lymph node - armpit	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-05-2020 10:39:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (pfe.banchp)	Query 1: Closed	Response satisfies query
Oct-05-2020 10:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-05-2020 10:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/4/2020 17:00	Transcription Error
Oct-05-2020 10:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Patricia Banchero (pfe.banchp)	Query 1: Opened	GPDCLIN: The event is deemed related to study treatment but start time is prior to vaccination. Please review and update as applicable. Otherwise, please clarify.
Oct-02-2020 15:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/4/2020 15:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-02-2020 15:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Sep/8/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151035

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-02-2020 15:39:51 (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
Oct-02-2020 15:39:51 (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
Oct-02-2020 15:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-02-2020 15:39:51 (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
Oct-02-2020 15:39:51 (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
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090177e196ae3fea\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

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151035

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-02-2020 15:39:51 (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
Oct-02-2020 15:39:51 (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
Oct-02-2020 15:39:51 (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
Oct-02-2020 15:39:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fea\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: 10151035

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-23-2020 13:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> Dec/15/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1015

Subject No: 10151035

Generated By: pfe.lewissc

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-23-2020 13:15:36 (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 and NOT confirmed t o have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3fea\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: 10151035

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-23-2020 13:15:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Dec/15/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-23-2020 13:15:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151035

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
Oct-05-2020 10:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-17-2020 12:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-17-2020 12:42:00 (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
Oct-05-2020 10:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/2/2020	Initial Entry
Aug-17-2020 12:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/16/2020	Initial Entry
Aug-17-2020 12:42:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/16/2020	Initial Entry

090177e196ae3fea\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151035

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 06:10:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Elizabeth Barnett (pfe.ebarnett)	Data Entry: Click Here to Enable	Initial Entry