

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: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

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: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/21/2020
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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: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10151089]
2.	Birth Date:	(b) (6)/1979
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/21/2020
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: 10151089

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Migraines]
	Start Date:	UNK/UNK/1991
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergies]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151089

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/21/2020
2.	Weight:	[185.0]
3.	Unit:	LB
4.	Height:	[65.0]
5.	Unit:	in
6.	Body Mass Index:	[30.8]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

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/21/2020
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:	

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/21/2020
2.	Randomization Number:	[60865]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8DW5]
5.b	Sample ID	[BM8DW6]
5.c	Sample ID	[BM8DW7]
5.d	Sample ID	[BLD05Y]
5.e	Sample ID	[BLD05Z]

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

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/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8DW1]
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151089

Generated By: pfe.lewissc

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/21/2020 15:05
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

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1015

Subject No: 10151089

Generated By: pfe.lewissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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/11/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/11/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

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/11/2020
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:	

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

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/11/2020
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	[BP9J1X]
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151089

Generated By: pfe.lewissc

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/11/2020 11:18
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

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

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	Oct/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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/9/2020
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	[BP9HMD]
5.b	Sample ID	[BRTRXV]
5.c	Sample ID	[BRTRXW]
5.d	Sample ID	[BRTRXX]

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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/8/2021
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	[BR70GW]
5.b	Sample ID	[BSH1L5]
5.c	Sample ID	[BSH1L6]
5.d	Sample ID	[BSH1L4]

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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: 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: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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: 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: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** DATE OF VISIT - ILLNESS ONSET Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

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 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 Visit

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** HEALTH CARE UTILIZATION
Visit

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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?	
----	--	--

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ILLNESS DETAILS
Visit

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

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 Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

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

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/12/2020

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: 10151089

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/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/12/2020

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: 10151089

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/12/2020

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: 10151089

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/12/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Called regarding eDiary symptoms reported. Is feeling better after taking tylenol. Will recontact us with further concerns. No need for swab or inperson visit.]

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

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/9/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.leviscc

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

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

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: 10151089

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	Fever	Sep/11/2020 22:00	NO End Date Time: Sep/13/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Whole arm pain - received injection	Sep/11/2020 22:00	NO End Date Time: Sep/13/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Swollen left axillary lymph node	Sep/11/2020 22:00	NO End Date Time: Sep/18/2020 UNK:UNK	Repeating Pages

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fever]
4.	Start Date Time:	Sep/11/2020 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/13/2020 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

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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

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

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1015**Subject No:** 10151089**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Whole arm pain - received injection]
4.	Start Date Time:	Sep/11/2020 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/13/2020 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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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

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

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Swollen left axillary lymph node]
4.	Start Date Time:	Sep/11/2020 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/18/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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

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

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

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: 10151089

Generated By: pfe.levisse

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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Medication Error

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

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flu vaccine	Oct/8/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flu vaccine]
5.	Date:	Oct/8/2020

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

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: 10151089

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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

Header Text: c4591001

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

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

Site No: 1015 **Site Name:** (1015) Boston Medical Center

Subject No: 10151089 **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: 10151089 **Subject Initials:** ---

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001**Visit:** Unplanned Vaccination - Unscheduled **Form:** LAB URINALYSIS - PREGNANCY TEST**Form Version:** 20-Feb-2021 02:14**Form Status:** Not Started**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151089**Subject Initials:** ---**Generated By:** pfe.lewissc**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:	

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: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089 **Subject Initials:** ---

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

Contact Outcome

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

Header Text: c4591001

Visit: 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: 10151089 **Subject Initials:** ---

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

Contact Outcome

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

Header Text: c4591001

Visit: 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: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

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

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: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

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: 10151089

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: 10151089

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: 10151089

Generated By: pfe.lewissc

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 Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.lewissc

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.lewissc

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/9/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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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: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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 10:38:10 (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: 10151089
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-21-2020 16:03:07 (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: 10151089

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 10:38:10 (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-08-2021 11:50:48 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Elizabeth Barnett	Approved	Jan-21-2021 19:21:30 (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 13:20:43 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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:** 10151089**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:21**Affidavit:**

N/A

Stephen Pelton	Approved	Nov-16-2020 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Taylor Stannard	N/A	Nov-12-2020 11:46:48 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Elizabeth Barnett	Approved	Oct-20-2020 20:18:22 (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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-21-2020 16:02:19 (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-21-2020 16:02:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-21-2020 16:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: OBTAINED Date Written Consent Obtai ned Aug/21/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-21-2020 16:02:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10151089	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-21-2020 16:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1979	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-21-2020 16:02:44 (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-21-2020 16:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORI GIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 16:02:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: WHITE	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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-21-2020 16:03:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/21/2020	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-21-2020 16:03:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-21-2020 16:03:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-21-2020 16:03:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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I.a

Date	Location	User	Value	Reason
Aug-21-2020 16:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Migraines Term: Start Date: UNK/UNK/ 1991 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 16:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Migraines	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-21-2020 16:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: UNK/UNK/1991	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 16:06:08	ACV0PFEINFP6000	Taylor	Data Entry:	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)		Stannard (pfe.tstannard)	YES	
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1.b

Date	Location	User	Value	Reason
Aug-21-2020 16:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: r: Medical History Allergies Term: Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 16:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Allergies	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-21-2020 16:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: UNK/UNK/1995	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-21-2020 16:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151089

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-21-2020 16:07:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/21/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-21-2020 16:07:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 185.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-21-2020 16:07:22 (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-21-2020 16:07:22 (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-21-2020 16:07:22 (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
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151089

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

Aug-21-2020 16:07:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.8	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-21-2020 16:07:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Record Identifier: Temperature: 98.6 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-21-2020 16:07:22 (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-21-2020 16:07:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 98.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-21-2020 16:07:22 (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
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151089

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

Aug-21-2020 16:07:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-21-2020 16:08:26 (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-21-2020 16:08:26 (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-21-2020 16:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/21/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-21-2020 16:08:26 (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-21-2020 16:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-21-2020 16:08:26 (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

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-21-2020 16:08:26 (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-21-2020 16:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-21-2020 16:08:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151089

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-21-2020 16:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/21/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-21-2020 16:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 60865	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

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
Aug-22-2020 17:38:08 (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-22-2020 17:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-22-2020 17:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-22-2020 17:38:08 (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-22-2020 17:38:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Aug/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-22-2020 17:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8DW5	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 17:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8DW5	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-22-2020 17:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8DW6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 17:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8DW6	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-22-2020 17:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8DW7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 17:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8DW7	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

5.d

Date	Location	User	Value	Reason
Aug-22-2020 17:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BLD05Y	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 17:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BLD05Y	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-22-2020 17:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BLD05Z	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 17:39:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BLD05Z	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151089**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-22-2020 17:39:47 (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-22-2020 17:39:47 (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-22-2020 17:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-22-2020 17:39:47 (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-22-2020 17:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Aug/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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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: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-22-2020 17:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BM8DW1	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-22-2020 17:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BM8DW1	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151089

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-21-2020 16:09:06 (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-21-2020 16:09:06 (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-21-2020 16:09:06 (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-21-2020 16:09:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Aug/21/2020 15:05	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-21-2020 16:09:06 (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
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151089

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

Aug-21-2020 16:09:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Aug-21-2020 16:09:06 (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-21-2020 16:09:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-21-2020 16:09:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1015

Subject No: 10151089

Generated By: pfe.lewissc

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-21-2020 16:11:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO - REACTOGENICITY E- DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-11-2020 13:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/11/2020	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151089

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-11-2020 13:20:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/11/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-11-2020 13:20:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Record Identifier 1 r:: Temperature: 98.0 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-11-2020 13:20:02 (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-11-2020 13:20:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-11-2020 13:20:02	ACV0PFEINFP6000	Taylor	Data Entry:	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151089

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

(UTC-05:00) Eastern Time (US & Canada)		Stannard (pfe.tstannard)	F	
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2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-11-2020 13:20:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-11-2020 13:21:37 (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
Sep-11-2020 13:21:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-11-2020 13:21:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/11/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-11-2020 13:21:37 (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
Sep-11-2020 13:21:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-11-2020 13:21:37 (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

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-11-2020 13:21:37 (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-11-2020 13:21:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-11-2020 13:21:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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:** 10151089**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-11-2020 18:25:48 (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-11-2020 18:25:48 (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-11-2020 18:26:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 18:25:48 (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-11-2020 18:25:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Sep/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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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: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-11-2020 18:26:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BP9J1X	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 18:26:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BP9J1X	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151089

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
Sep-11-2020 13:21:11 (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-11-2020 13:21:11 (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-11-2020 13:21:11 (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-11-2020 13:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/11/2020 11:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-11-2020 13:21:11 (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
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151089

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

Sep-11-2020 13:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Sep-11-2020 13:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-11-2020 13:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-11-2020 13:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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
Oct-09-2020 13:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Oct/9/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151089**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 12:24:30 (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-14-2020 12:24:30 (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-14-2020 12:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 12:24:30 (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-14-2020 12:24:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Oct/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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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: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

Oct-14-2020 12:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BP9HMD	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 12:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BP9HMD	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 12:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BRTRXV	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 12:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BRTRXV	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 12:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BRTRXW	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 12:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BRTRXW	Initial Entry

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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: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

5.d

Date	Location	User	Value	Reason
Oct-14-2020 12:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BRTRXX	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 12:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BRTRXX	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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-08-2021 11:50:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Mar/8/2021	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: 10151089

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
Mar-09-2021 15:36:33 (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-09-2021 15:36:33 (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-09-2021 15:36:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-09-2021 15:36:33 (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-09-2021 15:36:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Collection: Mar/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

Mar-09-2021 15:36:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BR70GW	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 15:36:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BR70GW	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-09-2021 15:40:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSH1L5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 15:40:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BSH1L5	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-09-2021 15:40:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSH1L6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 15:40:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BSH1L6	Initial Entry

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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: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

5.d

Date	Location	User	Value	Reason
Mar-09-2021 15:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sample ID: BSH1L4	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 15:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: BSH1L4	Initial Entry

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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/12/2020

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: 10151089

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-14-2020 11:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/12/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/12/2020

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: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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

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I. Assessments

Date	Location	User	Value	Reason
Sep-14-2020 11:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 11:26:28 (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-14-2020 11:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Sep/12/2020**Form:** CONTACT OUTCOME - UNPLANNED - 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:** 10151089**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Sep-14-2020 11:27:27 (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-14-2020 11:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES Date of Contact: Sep/12/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISI ON	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Nov-13-2020 05:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 2: Clo sed	Response satisfies query
Nov-12-2020 11:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 2: An swere d	Added to AE log, thanks!

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/12/2020

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151089

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

Nov-11-2020 00:16:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 2: Op ened	Subject not in the reactogenicity subset so unplanned contact CRF unwarranted. Please ensure that any adverse events reported during the contact are added to the AE log or SOD form under potential C-19 illness visit as appropriate. Thank you.
Nov-10-2020 16:32:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 2: Ca ndidat e	Subject not in the reactogenicity subset so unplanned contact CRF unwarranted. Please ensure that any adverse events reported during the contact are added to the AE log or SOD form under potential C-19 illness visit as appropriate. Thank you.

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/12/2020

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151089

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

Sep-16-2020 10:27:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Clo sed	Response satisfies query
Sep-15-2020 15:01:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: An swere d	This was regarding the COVID illness diary. Participant had been filling it out every day, we have since instructed him not to do so.
Sep-15-2020 12:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Op ened	Per Reactogenicity Diary eCRF the e-diary is not collected for this subject. For any symptoms, AEs, or other key data should be collected on the appropriate page or eDiary. If this is already in the predefined list above please choose the appropriate value. Please review and update as necessary.

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/12/2020

Form: CONTACT OUTCOME - UNPLANNED - 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: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

				"[vathm SDQ=7562]"
Sep-14-2020 11:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry : Called regarding eDiary symptoms reported. Is feeling better after taking tylenol. Will recontact us with further concerns. No need for swab or inperson visit.	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-09-2020 13:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Oct/9/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-09-2020 13:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-09-2020 13:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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

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Date	Location	User	Value	Reason
Nov-12-2020 11:46:48 (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: 10151089

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (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: 10151089

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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
Nov-12-2020 11:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-12-2020 11:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-12-2020 11:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Fever	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-12-2020 11:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/11/2020 22:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-12-2020 11:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Sep/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Nov-12-2020 11:46:48 (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
Nov-12-2020 11:46:48 (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
Nov-12-2020 11:46:48 (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
Nov-12-2020 11:46:48 (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
Nov-12-2020 11:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-12-2020 11:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-12-2020 11:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 11:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 11:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

Generated By: pfe.lewissc

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
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Whole arm pain - received inj ection	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/11/2020 22:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Sep/13/2020 UNK:UNK	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 11:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

Generated By: pfe.lewissc

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
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Swollen left axillary lymph node	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Sep/11/2020 22:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO End Date Time: Sep/18/2020 UNK:UNK	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151089

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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 11:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: NO	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Nov-12-2020 11:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levisse

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-12-2020 11:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-12-2020 11:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-12-2020 11:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Nov-12-2020 11:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Flu vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Nov-12-2020 11:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Oct/8/2020	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (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: 10151089

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 13:20:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: 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: 10151089

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Dec-23-2020 13:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-23-2020 13:20:43 (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 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-09-2020 13:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-21-2020 16:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-21-2020 16:03:22 (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-09-2020 13:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/9/2020	Initial Entry
Aug-21-2020 16:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/21/2020	Initial Entry
Aug-21-2020 16:03:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/21/2020	Initial Entry

090177e196ae3fec\Final\Final On: 01-Apr-2021 05:26 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151089

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-20-2020 20:18:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Elizabeth Barnett (pfe.ebarnett)	Data Entry: Click Here to Enable	Initial Entry