

**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:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/20/2020
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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:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10151071]
2.	Birth Date:	(b) (6) 1988
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:** 10151071

**Generated By:** pfe.lewissc

**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/20/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**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:** 10151071

**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/20/2020
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:** 10151071

**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

**Form Comments**

**Medical History Details**

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

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**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/20/2020
2.	Weight:	[117.0]
3.	Unit:	LB
4.	Height:	[67.0]
5.	Unit:	in
6.	Body Mass Index:	[18.3]

**Vital Signs Details**

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

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1015

**Subject No:** 10151071

**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/20/2020
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:	

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> RANDOMIZATION
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1015) Boston Medical Center
<b>Site No:</b> 1015	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10151071	<b>Generated Time (GMT):</b> 29-Mar-2021 04:21
<b>Generated By:</b> pfe.levissc	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Aug/20/2020
2.	Randomization Number:	[57976]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
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	[BLD04T]
5.b	Sample ID	[BLD04V]
5.c	Sample ID	[BM8FHJ]
5.d	Sample ID	[BM8FHK]
5.e	Sample ID	[BM8FHL]

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
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	[BM8FH8]
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090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1015

**Subject No:** 10151071

**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/20/2020 11:48
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	NO If No, specify reason: [Had to leave early for work. Did not report any AE's]

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**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/10/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/10/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/10/2020
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:	

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**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/10/2020
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	[BP9J0Z]
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090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/10/2020 10:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	NO If No, specify reason: [Patient had to leave urgently. Asked to contact us with any concerns. Expressed understanding.]

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/9/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/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	[BP9HML]
5.b	Sample ID	[BRTRYF]
5.c	Sample ID	[BRTRYG]
5.d	Sample ID	[BRTRYH]

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

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

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**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:	[ ]
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090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**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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090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**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?	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:	

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**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:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Unplanned Assessments**

1.	Assessments	
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090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** DISPOSITION - TREATMENT

**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 - 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 Version:** 15-Sep-2020 21:53

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

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

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**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:** 10151071

**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	Exposure during pregnancy	Jan/7/2021 UNK: UNK	YES	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

**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:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure during pregnancy]	
4.	Start Date Time:	Jan/7/2021 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	<a href="#">Comments</a>
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Unrelated]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**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.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

**Medication Error**

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

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**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.						<a href="#">Repeating Pages</a>

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**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.						<a href="#">Repeating Pages</a>

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1015  
**Subject No:** 10151071  
**Generated By:** pfe.levisse

**Form:** RADIATION TREATMENT  
**Form Status:** Not Started  
**Site Name:** (1015) Boston Medical Center  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:21

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**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:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**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:	

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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?	

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

<b>Header Text:</b> c4591001	<b>Form:</b> INFORMED CONSENT - FURTHER VACCINATION
<b>Visit:</b> V101_VAX3	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 10-Dec-2020 02:31	<b>Site Name:</b> (1015) Boston Medical Center
<b>Site No:</b> 1015	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10151071	<b>Generated Time (GMT):</b> 29-Mar-2021 04:21
<b>Generated By:</b> pfe.levissc	

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Dec/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:	

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/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	[BSN5CS]
5.b	Sample ID	[BSN5D2]
5.c	Sample ID	[BSN5D3]
5.d	Sample ID	[BRFKMZ]

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/21/2020 13:06
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**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:** 10151071

**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 :	//
----	------------------------------	----

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/11/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/11/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
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	[BRFKRY]
-----	-----------	----------

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/11/2021 11:01
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/16/2021
2.	Erroneous Visit	



**Header Text:** c4591001  
**Visit:** V103\_MONTH1  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1015  
**Subject No:** 10151071  
**Generated By:** pfe.levissc

**Form:** CONTACT OUTCOME  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1015) Boston Medical Center  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:21

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/16/2021
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**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 :	Feb/16/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**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:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
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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:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.leviscc

**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 10:32:42 (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.

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1015

**Subject No:** 10151071

**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-20-2020 11:39:23 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-20-2020 11:41:52 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Feb-24-2021 10:58:07 (UTC-05:00) Eastern Time (US & Canada)	Taylor Stannard (pfe.tstannard)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-21-2020 13:50:45 (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:** 10151071

**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 10:32:42 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

Taylor Stannard	N/A	Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Elizabeth Barnett	Approved	Jan-21-2021 19:15:57 (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-21-2020 13:50:05 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Elizabeth Barnett	Approved	Oct-20-2020 20:04:18 (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.

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Aug-20-2020 11:38:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:38:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

***I. Consent Was:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-20-2020 11:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1015

Subject No: 10151071

Generated By: pfe.levissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-20-2020 11:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10151071	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-20-2020 11:38:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1988	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-20-2020 11:39:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-20-2020 11:39:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A ) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:39:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-20-2020 11:39:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-20-2020 11:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-20-2020 11:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-20-2020 11:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1015

Subject No: 10151071

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> 117.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> 67.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 18.3	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1015

Subject No: 10151071

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

7.a

Date	Location	User	Value	Reason
Aug-20-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 97.9 <b>Temperature Unit</b> F : <b>Temperature Loc</b> ORAL CAV <b>ation::</b> ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-20-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-20-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-20-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-20-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151071

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:33 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151071

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-20-2020 11:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-20-2020 11:43:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-20-2020 11:43:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> 57976	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151071**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-21-2020 09:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-21-2020 09:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-21-2020 09:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 09:57:17 (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-21-2020 09:57:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES Date of Collection:  Aug/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-21-2020 09:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Sample ID:</b> BLD04T	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151071

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BLD04T	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-21-2020 09:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Sample ID: BLD04V</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BLD04V	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-21-2020 09:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Sample ID: BM8FHJ</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BM8FHJ	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-21-2020 09:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Sample ID: BM8FHK</b>	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 09:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BM8FHK	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-21-2020 09:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Sample ID:</b> BM8FHL	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 09:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BM8FHL	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151071**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
Aug-21-2020 09:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-21-2020 09:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-21-2020 09:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES Date of Collection:  Aug/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-21-2020 09:58:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Sample ID:</b> BM8FH8	Transcription Error
Aug-21-2020 09:58:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Sample ID:</b> BM8FH7	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 09:58:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BM8FH8	Transcription Error

**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:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Aug-21-2020 09:58:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BM8FH7	Initial Entry
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151071

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-20-2020 11:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-20-2020 11:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-20-2020 11:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-20-2020 11:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Aug/20/2020 11:48	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-20-2020 11:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-20-2020 11:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151071

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

7. Route:

Date	Location	User	Value	Reason
Aug-20-2020 11:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-20-2020 11:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 00:32:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Closed	closed per SITE response, added to PD review tracker
Aug-21-2020 09:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Original value is correct
Aug-21-2020 09:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Opened	PDQ: Response to question for observation post dose is 'NO'. Please review and correct or confirm.
Aug-20-2020 11:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO <i>If No, specify reason:</i>  Had to leave early for work. Did not report any AE's	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1015

**Subject No:** 10151071

**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

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-20-2020 11:43:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-10-2020 12:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Sep/10/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1015

Subject No: 10151071

Generated By: pfe.levissc

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Sep-10-2020 12:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Sep/10/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-10-2020 12:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 98.4 <b>Temperature Unit</b> F : <b>Temperature Loc</b> ORAL CAV <b>ation::</b> ITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-10-2020 12:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-10-2020 12:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> 98.4	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-10-2020 12:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> F	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

**2.a Temperature Location:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-10-2020 12:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151071

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Sep/10/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:24 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151071

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151071

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 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-11-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-11-2020 13:09:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 13:09:30 (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.
Sep-11-2020 13:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES Date of Collection:  Sep/10/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-11-2020 13:09:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Sample ID:</b> BP9J0Z	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-11-2020 13:09:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BP9J0Z	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151071

Generated By: pfe.lewiss

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Sep/10/2020 10:32	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-10-2020 12:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1015

Subject No: 10151071

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

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 12:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 12:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-10-2020 12:25:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO <i>If No, specify reason:</i>  Patient had to leave urgently. Asked to contact us with any concerns. Expressed understand ing.	New Information
Sep-10-2020 12:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-09-2020 15:15:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> 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:** 10151071**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
Oct-14-2020 12:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-14-2020 12:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-14-2020 12:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 12:30:18 (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 12:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES Date of Collection:  Oct/9/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-14-2020 12:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Sample ID:</b> BP9HML	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: 10151071

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 12:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BP9HML	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 12:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Sample ID: BRTRYF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 12:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BRTRYF	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 12:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Sample ID: BRTRYG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 12:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BRTRYG	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-14-2020 12:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Sample ID: BRTRYH	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.d Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-14-2020 12:44:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BRTRYH	Initial Entry

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-09-2020 15:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-09-2020 15:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-09-2020 15:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-24-2021 10:03:02 (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: 10151071

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-25-2021 09:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Clinical PG Safety event start date is 1st day of LMP (07Jan21). Please clarify date of positive urine PG test, would be a later date
Feb-24-2021 10:59:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Positive pregnancy test was on 7Jan2021 (start date)
Feb-24-2021 10:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Please submit a PG safety report update with the date of the positive urine pregnancy test
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Exposure during pregnancy	Initial Entry

**4. Start Date Time:**

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1015**Subject No:** 10151071**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1015) Boston Medical Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:21

Date	Location	User	Value	Reason
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Jan/7/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-25-2021 09:29:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-24-2021 10:58:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-24-2021 10:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-24-2021 10:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b>	Transcription Error
Feb-24-2021 10:47:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical As per CRF CG 8.50.2.5, the toxicity grade for "Exposure During Pregnancy" is reported as Not Applicable
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> 1	Initial Entry

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151071

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-25-2021 09:29:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Feb-24-2021 10:58:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-24-2021 10:58:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 10:58:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO	Changed Information
Feb-24-2021 10:48:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical As per CRF CG 8.50.2.5, an "Exposure During Pregnancy" is not an SAE [despite using similar forms to report pregnancy]; only abnormal outcomes of pregnancy are evaluated for serious criteria
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Exposure during pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birt	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1015

Subject No: 10151071

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

			h defect?  NO  Did this serious event result in death?  NO  Did this serious event require or prolong hospitalization?  NO  Did this serious event result in persistent or significant disability/incapacity?  NO  Is this serious event life threatening?  NO  Other medically important serious event  YES	
--	--	--	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--

**8. Is this adverse event the result of a study Medication Error?**  
*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151071

Subject Initials: ---

Generated By: pfe.levisse

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

			OTHER	
			<i>If Other, specify:</i>	
			Unrelated	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-25-2021 08:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Priyanka Nigade (pfe.nigadp)	Query 1: Closed	Response satisfies query
Feb-24-2021 10:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Pregnancy still continuing, unknown outcome
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Exposure during pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

				provided or "Is the adverse event still ongoing?" is marked "Yes".
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> UNKNOWN	Initial Entry

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

Date	Location	User	Value	Reason
Feb-24-2021 10:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO	Initial Entry

**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:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Dec-21-2020 13:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> 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:** 10151071

**Generated By:** pfe.lewissc

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-21-2020 13:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national reco mmendations and confirmed t o have received only placebo a t Vaccination 1/2	Initial Entry



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**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

[Back to Form](#)

*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-21-2020 13:50:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Dec/21/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

**1. Consent Was:**

Date	Location	User	Value	Reason
Dec-21-2020 13:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Dec/21/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Dec-21-2020 13:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Dec/21/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-21-2020 13:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-21-2020 13:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151071**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Dec/21/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:14 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151071

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151071**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
Dec-22-2020 10:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-22-2020 10:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-22-2020 10:26:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 10:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 10:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES Date of Collection:  Dec/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-22-2020 10:26:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Sample ID:</b> BSN5CS	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151071

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 10:26:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BSN5CS	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-22-2020 10:56:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Sample ID: BSN5D2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 10:56:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BSN5D2	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-22-2020 10:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Sample ID: BSN5D3	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 10:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BSN5D3	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-22-2020 11:25:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Sample ID: BRFKMZ	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.d Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-22-2020 11:25:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BRFKMZ	Initial Entry



**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151071**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
Dec-22-2020 11:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-22-2020 11:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-22-2020 11:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 11:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 11:54:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES Date of Collection:  Dec/21/2020	Initial Entry

**5.a**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Sample ID**

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

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1015

Subject No: 10151071

Generated By: pfe.lewiss

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Dec/21/2020 13:06	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1015

Subject No: 10151071

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

**7. Route:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Dec-21-2020 13:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-21-2020 13:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1015

Subject No: 10151071

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[Back to Form](#)

**I. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-24-2021 18:05:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_36
Feb-24-2021 10:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-24-2021 10:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry</b> : Dec/15/2020	Transcription Error
Feb-24-2021 02:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Reissued: Opened	DM: Per response, DISPOSITION CRF unfrozen. Kindly review and update.
Feb-23-2021 13:04:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	please unfreeze disposition so i can update, thanks
Feb-23-2021 00:44:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7351185;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

				ADDITIONAL VACCINATION. Please review and update as appropriate.
Dec-21-2020 13:50:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry</b> : Dec/14/2020	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Dec-21-2020 13:50:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-11-2021 13:35:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151071

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:00 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)



Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1015

Site Name: (1015) Boston Medical Center

Subject No: 10151071

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001**Visit:** V102\_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151071**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-15-2021 12:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-15-2021 12:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-15-2021 12:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES Date of Collection:  Jan/11/2021	Transcription Error
Jan-15-2021 12:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-15-2021 12:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-15-2021 12:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES Date of Collection:  Jan/12/2021	Initial Entry

**5.a**

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1015

**Site Name:** (1015) Boston Medical Center

**Subject No:** 10151071

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Date	Location	User	Value	Reason
Jan-15-2021 12:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> <b>Sample ID:</b> BRFKRY	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-15-2021 12:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> BRFKRY	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1015

Subject No: 10151071

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Jan/11/2021 11:01	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1015

Subject No: 10151071

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1015) Boston Medical Center

Subject Initials: ---

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

**7. Route:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-11-2021 13:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 13:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**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

[Back to Form](#)

**I. Date of Visit**

Date	Location	User	Value	Reason
Mar-08-2021 00:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 1: Closed	Per site confirmation_PD tracker updated
Mar-05-2021 09:28:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Could not contact patient until this day. PD logged
Mar-05-2021 03:41:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	PDQ: Date of visit V103_MONTH1 is out of window for 1 days from V102_VAX4 DOV or Vaccination date. Please verify and update. Else, confirm in query response appropriately. "[rajkun SDQ=150143]"
Mar-04-2021 10:47:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> Feb/16/2021	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

**1. Contact Type:**

Date	Location	User	Value	Reason
Mar-04-2021 10:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Mar-04-2021 10:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> YES Date of Contact:  Feb/16/2021	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1015**Site Name:** (1015) Boston Medical Center**Subject No:** 10151071**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:21[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-05-2021 03:27:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clos ed	Auto closed by Validation Check: VC_DS001_21
Mar-04-2021 18:27:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW7601968;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-04-2021 10:47:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data E ntry:</b> Feb/16/ 2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-04-2021 10:47:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-04-2021 10:47:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	<b>Data Entry:</b> COMPLETED	Initial Entry



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.lewissc

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Oct-09-2020 15:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-20-2020 11:43:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-20-2020 11:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Mar-04-2021 15:52:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Donna Brandt- VanBlarcom (pfe.brandd01)	Query 2: Closed	Response satisfies query
Mar-04-2021 10:47:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 2: Answered	Changed data per query
Mar-04-2021 02:15:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Natasha Rajkumar (pfe.rajkun)	Query 2: Opened	DM: V103 overdue based on expected visit window. Please enter data or, if visit will never occur, mark Date of Visit as Not Done with form level comment. If subject is no longer in the trial, complete the Disposition FUP form & Disposition- Treatment(EOT2)
Feb-24-2021 10:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levisse

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

Feb-24-2021 10:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Taylor Stannard (pfe.tstannard)	Query 1: Answered	Changed data per query
Feb-22-2021 09:27:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - a PG safety report (2021168713) has be submitted; however, the event 'Exposure during Pregnancy' has not been reported on the AE CRF; please update AE CRF
Oct-09-2020 15:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Initial Entry
Aug-20-2020 11:43:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/20/2020	Initial Entry
Aug-20-2020 11:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

090177e196ae3fe5\Final\Final On: 01-Apr-2021 05:25 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1015

**Subject No:** 10151071

**Generated By:** pfe.levissc

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1015) Boston Medical Center

**Subject Initials:** ---

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

[Back to Form](#)

*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-20-2020 20:03:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Elizabeth Barnett (pfe.ebarnett)	<b>Data Entry:</b> Click Here to Enable	Initial Entry