

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1001

Subject No: 10011135

Generated By: pfe.levisse

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[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: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/5/2020
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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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10011135]
2.	Birth Date:	(b) (6)/1975
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: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[Form Comments](#)

Inclusion Criteria Not Met

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

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

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/5/2020
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: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[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 _____

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/5/2020
2.	Weight:	[56.5]
3.	Unit:	kg
4.	Height:	[169.0]
5.	Unit:	cm
6.	Body Mass Index:	[19.8]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/5/2020
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:	

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/5/2020
2.	Randomization Number:	[43218]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/5/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BMR2NB]
5.b	Sample ID	[BMR2NC]
5.c	Sample ID	[BP769M]
5.d	Sample ID	[BP769N]
5.e	Sample ID	[BP769P]

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/5/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP769F]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[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/5/2020 16:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/24/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	EAR

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/24/2020
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:	

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
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	[BP76KZ]
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[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/24/2020 15:47
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Sep/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
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	[BNW7KW]
5.b	Sample ID	[BNW7L1]
5.c	Sample ID	[BP76RZ]

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
----	-------------------------	--

Header Text: c4591001

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

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

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

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

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

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.leviscc

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Sep/23/2020
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: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Incomplete, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Left axilla lymphadenopathy	Jan/15/2021 UNK: UNK	NO End Date Time: Jan/26/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Left arm pain at injection site	Jan/15/2021 UNK: UNK	NO End Date Time: Feb/16/2021 UNK:UNK	Repeating Pages

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[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)	[Left axilla lymphadenopathy]
4.	Start Date Time:	Jan/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/26/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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 - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left arm pain at injection site]
4.	Start Date Time:	Jan/15/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/16/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[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	[]

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[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:	//

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[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?	

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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:	

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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?	

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/12/2021
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

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

[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: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/12/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/14/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Jan/14/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/14/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNW7PC]
5.b	Sample ID	[BNW7PD]
5.c	Sample ID	[BP27CY]

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/14/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP27CZ]
-----	-----------	----------

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/14/2021 12:58
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/19/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/19/2021
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:	

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/19/2021
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	[BP27GW]
-----	-----------	----------

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[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:	Feb/19/2021 11:38
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

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/23/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levisse

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

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-05-2020 19:07:09 (UTC-05:00) Eastern Time (US & Canada)	Sara Hyman (pfe.shyman)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-05-2020 19:07:55 (UTC-05:00) Eastern Time (US & Canada)	Sara Hyman (pfe.shyman)	no pertinent medical history <hr/> 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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
Form	Jan-21-2021 12:03:33 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	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, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Nazia Ria	N/A	Jan-15-2021 10:22:19 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Mark Mulligan	Approved	Oct-11-2020 20:46:27 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, MarkMulligan, 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.

Sara Hyman	N/A	Sep-23-2020 14:59:39 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
------------	-----	---	--	-----------------------------------

Affidavit:

N/A

Mark Mulligan	Approved	Sep-15-2020 10:37:41 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, MarkMulligan, 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.

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-05-2020 18:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 18:15:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-05-2020 18:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: OBTAINED Date Written Consent Obtained Aug/5/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-05-2020 18:15:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10011135	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-05-2020 18:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1975	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-05-2020 18:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-05-2020 18:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 18:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: WHITE	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-05-2020 18:31:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: Aug/5/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-05-2020 18:37:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: Aug/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-05-2020 18:37:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-05-2020 18:37:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Aug/5/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 56.5	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 169.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19.8	Initial Entry

7.a

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-05-2020 19:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Record Identifier:: 1 Temperature: 36.7 Temperature Unit: C Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 36.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Aug/5/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-05-2020 19:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-05-2020 19:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Aug-05-2020 19:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-05-2020 19:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-05-2020 19:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Aug/5/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-05-2020 19:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 43218	Initial Entry

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
 Form Version: 22-Apr-2020 21:03
 Site No: 1001
 Subject No: 10011135
 Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
 eCRF Audit Trail History
 Form Status: Data Complete, Locked, Frozen, Verified
 Site Name: (1001) NYU Langone Health
 Subject Initials: ---
 Generated Time (GMT): 29-Mar-2021 04:04

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1. Data Origin

Date	Location	User	Value	Reason
Aug-05-2020 18:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-05-2020 18:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-05-2020 18:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-05-2020 18:38:10 (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.
Aug-05-2020 18:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: YES Date of Collection: Aug/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-05-2020 18:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: Sample ID: BMR2NB	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-05-2020 18:38:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: BMR2NB	Initial Entry
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5.b

Date	Location	User	Value	Reason
Aug-05-2020 18:38:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: Sample ID: BMR2NC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 18:38:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: BMR2NC	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-05-2020 18:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: Sample ID: BP769M	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 18:38:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: BP769M	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-05-2020 18:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: Sample ID: BP769N	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 18:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: BP769N	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levisse

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

5.e

Date	Location	User	Value	Reason
Aug-05-2020 18:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: Sample ID: BP769P	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 18:39:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: BP769P	Initial Entry

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
 Form Version: 22-Apr-2020 21:03
 Site No: 1001
 Subject No: 10011135
 Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
 Audit Trail History
 Form Status: Data Complete, Locked, Frozen, Verified
 Site Name: (1001) NYU Langone Health
 Subject Initials: ---
 Generated Time (GMT): 29-Mar-2021 04:04

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1. Data Origin

Date	Location	User	Value	Reason
Aug-05-2020 18:37:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-05-2020 18:37:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-05-2020 18:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-05-2020 18:37:56 (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-05-2020 18:37:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: YES Date of Collection: Aug/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-05-2020 18:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: Sample ID: BP769F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Aug-05-2020 18:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Stephanie Rettig (pfe.srettig)	Data Entry: BP769F	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-05-2020 19:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-05-2020 19:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-05-2020 19:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-05-2020 19:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Aug/5/2020 16:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-05-2020 19:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-05-2020 19:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-05-2020 19:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-05-2020 19:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION 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-05-2020 19:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: YES	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-05-2020 19:09:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: YES - REACTOGENICITY E-DIAR Y COLLECTED FOR THIS SUBJE CT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-24-2020 14:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: FAT IG UE	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> <u>Symptom::</u> HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

2.d

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: CH ILL S Were fever or systemic sympt oms present on the last day t he Subject Diary was comple ted?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym ptoms present on the last da y the Subject Diary was co mpleted?: NO	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

2.e Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sym ptoms present on the last da y the Subject Diary was com pleted?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: NEW OR WORSE ED MUSC LE PAIN Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?: NO	Initial Entry
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2.g Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NEW OR WORSE NED MUSCLE P AIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: NEW OR WORSE NED JOIN T PAIN Were fever or systemic symptoms present on t he last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Symptom:

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51	ACV0PFEINFP6000	Akeem	Data Entry:	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

(UTC-05:00) Eastern Time (US & Canada)		Moore (pfe.amoore1)	REDNESS	
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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I. Date:

Date	Location	User	Value	Reason
Aug-24-2020 17:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> Aug/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-24-2020 17:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 37.0 Temperature Unit: C Temperature Location:: EAR	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-24-2020 17:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Aug-24-2020 17:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> 37.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-24-2020 17:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Aug-24-2020 17:06:07 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Akeem Moore	<u>Data Entry:</u> EAR	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

(US & Canada)

(pfe.amoore1)

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-24-2020 17:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-24-2020 17:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-24-2020 17:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Aug/24/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-24-2020 17:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-24-2020 17:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-24-2020 17:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Aug-24-2020 17:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-24-2020 17:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-24-2020 17:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-24-2020 14:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-24-2020 14:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-24-2020 16:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-24-2020 14:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-24-2020 14:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-24-2020 16:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Sample ID: BP76KZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Aug-24-2020 16:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: BP76KZ	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-24-2020 17:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-24-2020 17:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-24-2020 17:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-24-2020 17:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Aug/24/2020 15:47	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-24-2020 17:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-24-2020 17:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-24-2020 17:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-24-2020 17:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION 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 17:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: YES	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-23-2020 14:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Sep/23/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011135**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**I. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Symptom:: FAT IG UE	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

2.d

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Symptom:: CH ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

2.e Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> Symptom:: DIA RR HE A Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Symptom:: NEW OR WORSE ED MUSC LE PAIN Were fever or systemic symptoms present on t he last day the Subject Diary was completed?:	Initial Entry
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2.g Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NEW OR WORSE NED MUSCLE P AIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Symptom:: NEW OR WORSE NED JOIN T PAIN Were fever or systemic symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed? :	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52	ACV0PFEINFP6000	Sara Hyman	Data Entry:	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011135**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04(UTC-05:00) Eastern Time
(US & Canada)

(pfe.shyman)

REDNESS

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Injection Site Reaction:: PAIN A T INJEC TION SI TE	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 15:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-23-2020 16:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 16:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 16:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 16:34:56 (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-23-2020 16:34:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: YES Date of Collection: Sep/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 16:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Sample ID: BNW7KW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-23-2020 16:35:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: BNW7KW	Initial Entry
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5.b

Date	Location	User	Value	Reason
Sep-23-2020 16:35:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Sample ID: BNW7L1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 16:35:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: BNW7L1	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-23-2020 16:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Sample ID: BP76RZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 16:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: BP76RZ	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-24-2020 08:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Sep/23/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-24-2020 08:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-24-2020 08:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Incomplete, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-22-2021 13:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry:	entered in AE log
Feb-19-2021 14:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Feb/5/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-22-2021 13:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	entered in AE log
Feb-19-2021 14:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-22-2021 13:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-22-2021 13:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-22-2021 13:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry:	entered in AE log
Feb-19-2021 14:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Feb-19-2021 14:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Incomplete, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

				the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Feb-19-2021 14:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: ADVERSE EVENT	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Feb-22-2021 13:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry:	entered in AE log
Feb-19-2021 14:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Left axilla lymphadenopathy	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Left axilla lymphadenopathy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/15/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO End Date Time: Jan/26/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: 2	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-19-2021 14:38:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> RELATED	entry error
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Left axilla lymphadenopathy	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-19-2021 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 14:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

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Header Text: c4591001

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Site No: 1001

Subject No: 10011135

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Left arm pain at injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/15/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-22-2021 22:27:00 (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_AE001_10_AN
Feb-22-2021 14:12:02 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Query 1: Ans wered	This data is correct

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Canada)				
Feb-20-2021 20:58:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7331203;'End Date' is after 'Date of Completion/Discontinuation/Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO End Date Time : Feb /16/ 202 1 U NK :U NK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-19-2021 14:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 14:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-27-2021 07:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/12/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Jan-15-2021 10:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-15-2021 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/12/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-15-2021 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: ASSESS ELIGIBILITY FOR ADDIT IONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-22-2021 01:33:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Jan-21-2021 12:03:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Query 1: Answered	Not Applicable by selected
Jan-21-2021 02:17:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloi (pfe.moloim)	Query 1: Reissued:Opened	DM: Since Participant meets all inclusion criteria and no exclusion criteria .Please consider to record Inclusion/Exclusion Criteria as Not applicable.
Jan-20-2021 14:30:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Query 1: Answered	What do you want me to complete in the 'Inclusion/Exclusion Criteria'? Please see the options provided. Participant meets all inclusion criteria and no exclusion criteria. No options to select that choice.
Jan-20-2021 12:17:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashexhar Reddy (pfe.reddy51)	Query 1: Opened	DM: Kindly review and complete 'Inclusion/Exclusion Criteria - Further Vaccination form' at this visit. Thank you.
Jan-15-2021 10:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/14/2021	data correction
Jan-15-2021 10:22:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/15/2021	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-15-2021 10:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: OBTAINED Date Written Consent Obtained Jan/14/2021	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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-15-2021 10:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/14/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-15-2021 10:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-15-2021 10:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-15-2021 10:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-15-2021 10:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-15-2021 10:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/14/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-15-2021 10:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-15-2021 10:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-15-2021 10:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Jan-15-2021 10:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-15-2021 10:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-15-2021 10:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-15-2021 10:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-15-2021 10:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-15-2021 10:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-15-2021 10:23:57 (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 10:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES Date of Collection: Jan/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-15-2021 10:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID: BNW7PC	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-15-2021 10:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: BNW7PC	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jan-15-2021 10:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID: BNW7PD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-15-2021 10:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: BNW7PD	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-15-2021 10:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID: BP27CY	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-15-2021 10:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: BP27CY	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-15-2021 10:24:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-15-2021 10:24:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-15-2021 10:25:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-15-2021 10:24:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-15-2021 10:24:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES Date of Collection: Jan/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-15-2021 10:25:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID: BP27CZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Jan-15-2021 10:25:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: BP27CZ	Initial Entry
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Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-15-2021 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-15-2021 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-15-2021 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-15-2021 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/14/2021 12:58	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-15-2021 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-15-2021 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jan-15-2021 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-15-2021 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-15-2021 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-15-2021 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 10:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 03:25:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rose Madelein (pfe.rose19)	Query 1: Clo sed	Response satisfies query
Feb-23-2021 02:02:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 3: Clo sed	Closed per SITE response, added to PD tracker for Clinical Review
Feb-22-2021 22:27:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Clo sed	Auto closed by Validation Check: VC_SV001_04_AN
Feb-22-2021 14:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Query 3: Ans wered	This data is correct
Feb-22-2021 14:11:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Query 2: Ans wered	This data is correct.
Feb-22-2021 13:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Answer Auto Query
Feb-22-2021 08:36:22 (UTC-05:00)	ACV0PFEINFP6000	Malerato Moloim (pfe.moloim)	Query 1: Rei ssued:	DM: Thank you, please note that there cannot be a date that is after the date of

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

Eastern Time (US & Canada)			Opened	disposition follow-up. Please update as appropriate.
Feb-22-2021 01:21:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 3: Opened	PDQ: Date of visit V102_VAX4 is out of window for 13 days from V101_VAX3 Dose Date. Please verify and update. Else, confirm in query response appropriately. "[rajkun SDQ=134289]"
Feb-20-2021 20:58:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Opened	DMW7331186;'Date of Visit' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Feb-19-2021 15:08:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Query 1: Answered	data is correct. Subject still active in study.
Feb-19-2021 14:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Visit is after the Date of Completion/Discontinuation /Death on the Follow-Up Disposition form. Please review and update as appropriate.
Feb-19-2021 12:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry Feb/19/2021	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-19-2021 12:50:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-19-2021 12:50:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-22-2021 22:17:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_05_AN
Feb-22-2021 14:11:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Query 1: Answered	This data is correct
Feb-20-2021 20:32:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7331090;'Collection Date' is after 'Date of Completion/Discontinuation/Death' on the Disposition <- Follow-up> eCRF. Please clarify or correct.
Feb-19-2021 12:50:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Feb/19/2021	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levisse

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

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Feb-19-2021 12:50:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-19-2021 12:50:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-19-2021 12:50:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-19-2021 12:50:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-19-2021 12:50:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-19-2021 12:50:12 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

(US & Canada)				
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-19-2021 12:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-19-2021 12:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-19-2021 15:08:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-19-2021 12:43:45 (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.
Feb-19-2021 12:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES Date of Collection: Feb/19/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-19-2021 15:08:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID: BP27GW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (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: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.levissc

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

Feb-19-2021 15:08:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: BP27GW	Initial Entry
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Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-19-2021 12:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-19-2021 12:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-19-2021 12:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-19-2021 12:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Feb/19/2021 11:38	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-19-2021 12:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-19-2021 12:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: RIGHT	Initial Entry

7. Route:

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011135

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Feb-19-2021 12:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-19-2021 12:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-19-2021 12:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-19-2021 12:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-19-2021 12:53:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES	Initial Entry

090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1001**Subject No:** 10011135**Generated By:** pfe.levissc**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1001) NYU Langone Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Feb-22-2021 13:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	entered in AE log
Feb-19-2021 14:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Sep-24-2020 08:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-05-2020 19:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-05-2020 18:37:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-22-2021 13:52:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	entered in AE log
Feb-22-2021 13:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	entered in AE log
Feb-19-2021 14:29:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Feb/5/2021	Initial Entry
Sep-24-2020 08:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/23/2020	Initial Entry
Aug-05-2020 19:09:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/5/2020	Initial Entry
Aug-05-2020 18:37:40 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/5/2020	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011135

Generated By: pfe.lewissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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090177e196ae2f43\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011135

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-11-2020 17:30:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Click Here to Enable	Initial Entry