

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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	30 JUN 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: 10011093

Generated By: pfe.levissc

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 Jul/29/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1001

Subject No: 10011093

Generated By: pfe.levissc

Form: DEMOGRAPHY

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](#)

Demography

1.	Subject ID	[10011093]
2.	Birth Date:	(b) (6)/1961
3.	Sex:	MALE
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: 10011093

Generated By: pfe.levisse

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	Jul/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011093

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

[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00
1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00
1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

Exclusion Criteria

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Site No: 1001

Subject No: 10011093

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00
2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00

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Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011093

Generated By: pfe.lewissc

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

2 f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2 h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1001

Subject No: 10011093

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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2 k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.1	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2 m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

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	Jul/29/2020
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: 10011093

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendicitis]
	Start Date:	Jun/UNK/2004
	Ongoing:	NO End Date: Jun/UNK/2004
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bilateral cataracts]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2020
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[osteoarthritis]
	Start Date:	UNK/UNK/1994
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[pectus excavatum]
	Start Date:	UNK/UNK/1964
	Ongoing:	NO End Date: Jun/UNK/1964

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

Generated By: pfe.levissc

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Torn Anterior cruciate ligament]
	Start Date:	Dec/UNK/2000
	Ongoing:	NO End Date: Dec/UNK/2000
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hernia, inguinal, left]
	Start Date:	UNK/UNK/1979
	Ongoing:	NO End Date: UNK/UNK/1979
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hernia, inguinal, right]
	Start Date:	UNK/UNK/1997
	Ongoing:	NO End Date: UNK/UNK/1997

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1001

Subject No: 10011093

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:	Jul/29/2020
2.	Weight:	[101.1]
3.	Unit:	kg
4.	Height:	[189.5]
5.	Unit:	cm
6.	Body Mass Index:	[28.2]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.4]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

Generated By: pfe.lewissc

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 :	Jul/29/2020
2.	Randomization Number:	[220088]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

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: Jul/29/2020
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	[BP773V]
5.b	Sample ID	[BP773W]
5.c	Sample ID	[BP773X]
5.d	Sample ID	[BMR2HF]
5.e	Sample ID	[BMR2HD]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

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: Jul/29/2020
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	[BP7736]
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090177e196ae2f44\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: 10011093

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:	Jul/29/2020 13:15
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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1001

Subject No: 10011093

Generated By: pfe.levisc

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: 10011093

Generated By: pfe.levisse

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/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 17-Jul-2020 21:54

Site No: 1001

Subject No: 10011093

Generated By: pfe.levissc

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES

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 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

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Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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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 WORSENER MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENER 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

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1001

Subject No: 10011093

Generated By: pfe.levissc

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/19/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	EAR

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

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/19/2020
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	[BP76H8]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011093

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/19/2020 13:00
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

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011093

Generated By: pfe.levisse

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	Sep/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

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

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

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 WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
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

090177e196ae2f44\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: 10011093

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BMR2XM]
5.b	Sample ID	[BMR2XW]
5.c	Sample ID	[BP76RB]

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011093

Generated By: pfe.levisse

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/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Queries, 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?	NO
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	Not Applicable _____	Comments
		[]	
5.b	Sample ID	Not Applicable _____	Comments
		[]	
5.c	Sample ID	Not Applicable _____	Comments
		[]	

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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011093

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011093

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: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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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090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/13/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Jan/13/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/13/2021
2.	Date of First Symptom Started:	Jan/11/2021
3.	Symptoms Ongoing?	YES

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	YES
4.d	Symptoms:	CHILLS
	Was symptom present?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Jan/13/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

5.	Symptoms - Other Text:	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jan/13/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Microbiology Specimen

1.	Actual Date of Collection:	Jan/13/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[NALT Unknown]

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Jan/21/2021
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	[CV07749]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[not needed per protocol]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Jan/13/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	--	----

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

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Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 17-Jul-2020 21:53

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

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Lab Chemistry Details

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 17-Jul-2020 21:53

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

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Laboratory Data Hematology

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

5 h	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.i	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

5.j	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 17-Jul-2020 21:53

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ []	Comments
	Diastolic:	Not Applicable _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Applicable _____ []	Comments
	Heart Rate in beats/minute:	Not Applicable _____ []	Comments

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 17-Jul-2020 21:54

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Jan/13/2021

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Jan/13/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

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Imaging

1.	Date of Assessment:	Not Done _____ //	Comments
2.	Location of Assessment:	Not Done _____	Comments
3.	Type of Imaging Exam:	Not Done _____	Comments
4.	Assessment:	Not Done _____	Comments

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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Feb/10/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Visit on Feb/10/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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: Feb/10/2021
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	[BP27G7]	Comments
5.b	Sample ID	[BNW7SK]	Comments
5.c	Sample ID	[BNW7SL]	Comments

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/21/2020

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: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/21/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Aug/21/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Aug/21/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[]

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1001

Subject No: 10011093

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT

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 - Treatment

1.	Date of Completion/Discontinuation/Death :	Sep/21/2020
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: 10011093

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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: 10011093

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

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: 10011093

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 On going	Form Instance
1.	ADVERSE EVENT	1	Chest Pain	Jan/10/2021 12:09	NO End Date Time: Jan/15/2021 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011093

Generated By: pfe.levisse

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chest Pain]
4.	Start Date Time:	Jan/10/2021 12:09
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/15/2021 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).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011093

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

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [cardiac ischemia]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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	[2021030659]

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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: 10011093

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1001

Subject No: 10011093

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

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Medication Error

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

090177e196ae2f44\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: 10011093

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.	1	VACCINATIONS	NO	flu vaccine	Sep/14/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[flu vaccine]
5.	Date:	Sep/14/2020

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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: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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: 10011093

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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Concomitant Medications

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

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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: 10011093

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: 10011093

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae2f44\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: 10011093

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

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: 10011093

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: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

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?	

090177e196ae2f44\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: 10011093

Subject Initials: ---

Generated By: pfe.levisc

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: 10011093

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: V201_SURVEIL_CONSENT -
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: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

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

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: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/21/2021
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, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

Generated By: pfe.levisse

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/21/2021
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: 10011093

Subject Initials: ---

Generated By: pfe.levisc

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

Withdrawal Of Consent

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

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

Generated By: pfe.levissc

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1001) NYU Langone Health

Subject Initials: ---

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: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

Generated By: pfe.lewissc

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/21/2020

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: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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
------	----------------------	------	------	--------

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Queries, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
5.a	Mar-09-2021 11:03:36 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Queries, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
5.b	Mar-09-2021 11:05:04 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Queries, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
5.c	Mar-09-2021 11:05:22 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
1	Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2	Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
3	Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
4	Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5	Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
6	Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Jan-26-2021 13:47:12 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
1	Jan-26-2021 13:47:12 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2	Jan-26-2021 13:47:12 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
3	Jan-26-2021 13:47:12 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
4	Jan-26-2021 13:47:12 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
Form	Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
1	Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2	Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
3	Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
4	Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5.a	Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5.a	Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5.a	Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5.a	Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5.b	Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
5.b	Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

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Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
3	Jan-26-2021 13:45:01 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
Form	Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
1	Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2	Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
3	Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
4	Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5	Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
6	Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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Item	Date	User	Comment
Form	Jan-26-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
1	Jan-26-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
2	Jan-26-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
3	Jan-26-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
4	Jan-26-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Done

Header Text: c4591001

Visit: POT_COVID_CONVA 1

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5.a	Mar-09-2021 09:41:31 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	
5.a	Feb-10-2021 13:51:54 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_CONVA 1

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5.b	Mar-09-2021 09:42:33 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	
5.b	Feb-10-2021 13:52:43 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_CONVA 1

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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Item	Date	User	Comment
5.c	Mar-09-2021 09:42:50 (UTC-05:00) Eastern Time (US & Canada)	Nazia Ria (pfe.nria)	
5.c	Feb-10-2021 13:53:02 (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: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Mark Mulligan	Approved	Oct-11-2020 20:18:20 (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.

Mahnoor Ali	N/A	Sep-21-2020 13:54:36 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Mulligan	Approved	Aug-26-2020 21:12:27 (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.

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:54

Site No: 1001

Subject No: 10011093

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
Jul-29-2020 13:16:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 13:16:31 (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: 10011093

Generated By: pfe.levissc

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
Jul-29-2020 13:16:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: OBTAINED Date Written Consent Obtained Jul/29/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1001

Subject No: 10011093

Generated By: pfe.levissc

Form: DEMOGRAPHY - 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. Subject ID

Date	Location	User	Value	Reason
Jul-29-2020 13:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10011093	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jul-29-2020 13:16:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1961	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jul-29-2020 13:16:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jul-29-2020 13:16:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 13:16:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: WHITE	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.levisse

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
Jul-29-2020 13:17:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Jul/29/2020	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Inclus ion N umber: riter Male or female participan ion De ts between the ages of 18 scripti and 55 years, inclusive, 6 on: 5 and 85 years, inclusive, or 18 and 85 years, inclusi ve, at randomization (dep endent upon study stage) riter YES ion m et?: riter IN01A00 ion ID : (For Pfizer use on ly):	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Male or female participants betwe en the ages of 18 and 55 years, inc lusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at ra	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

			ndomization (dependent upon study stage)	
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1.a Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: YES	Initial Entry

1.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Inclusion Number: Criteria Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures Criteria met?: Criteria ID: (For Pfizer use only):	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04***1.b Inclusion Number:***

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

1.b Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: YES	Initial Entry

1.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: IN02A00	Initial Entry

1.c

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Inclusion Number:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

			<p>Criteria Healthy participants who on Des are determined by medical criteria history, physical examination, n: ation, and clinical judgment of the investigator to be eligible for inclusion in the study</p> <p>Criteria YES on met ?:</p> <p>Criteria IN03A00 on ID: (For Pfizer use only):</p>	
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090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04***I.c Inclusion Number:***

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: YES	Initial Entry

I.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Inclusion Number:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

			<p>Criteria Capable of giving person on Des al signed informed conse criptio nt, which includes compl n: iance with the requireme nts and restrictions listed in the ICD and in this pro tocol</p> <p>Criteria YES on met ?:</p> <p>Criteria IN04A00 on ID: (For P fizer u se only):</p>	
--	--	--	--	--

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**1.d Inclusion Number:**

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

1.d Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: YES	Initial Entry

1.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Exclus 1 ion Nu mber:	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04

			<p>Criterion Description: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX01A00</p> <p>Reason: (For Pfizer use only):</p>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.a Criterion ID: (For Pfizer use only)

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Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Exclusion Number: Criterion Description: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) Criterion met?: NO Criterion ID: (For Pfizer use only): EX02A00	Initial Entry

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Subject No: 10011093

Subject Initials: ---

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2.b Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Exclusion Number:	Initial Entry

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Header Text: c4591001

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Site Name: (1001) NYU Langone Health

Subject No: 10011093

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			<p>Criteria History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)</p> <p>Criteria NO</p> <p>Criteria met</p> <p>Criteria ID: EX03A00</p> <p>(For Pfizer use only)</p>	
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Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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2.c Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Exclusion Number: 4 Criterion Description: Receipt of medications intended to prevent COVID-19	Initial Entry

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Subject No: 10011093

Subject Initials: ---

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			Criterion met? Criterion ID EX04A00 : (For Pfizer use only):
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2.d Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Exclusion Number:	Initial Entry

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			<p>Criteria on Description: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</p> <p>Criteria met?: NO</p> <p>Criteria ID: EX08A00 (For Pfizer use only)</p>	
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Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Immunocompromised individuals with known or suspected immuno- deficiency, as determined by histo- ry and/or laboratory/physical exa- mination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.e Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Exclus 10 ion Nu mber:	Initial Entry

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Subject No: 10011093

Generated By: pfe.levissc

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			<p>Criterion Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p>Criterion ID: NO</p> <p>Criterion Met: ?</p> <p>Criterion ID: EX10A00</p> <p>(For Pfizer use only):</p>	
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2.f Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Bleeding diathesis or condition as associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.f Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding	Initial Entry

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Subject Initials: ---

Generated By: pfe.levisse

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			Criterion met NO ?: Criterion ID: EX11A00 (For Pfizer use only):	
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.g Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Exclusion Number: 12	Initial Entry

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Subject Initials: ---

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			Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: EX12A00 (For Pfizer use only):	
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.h Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
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<p>Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Mahnoor Ali (pfe.mali1)</p>	<p>Data Entry: Exclusion Number: 13 Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids Criterion met?: NO Criterion ID: (For Pfizer use only): EX13A01</p>	<p>Initial Entry</p>
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2.i Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.i Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Exclus 15 ion Nu mber:	Initial Entry

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			<p>Criterion Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study</p> <p>Criterion Met?: NO</p> <p>Criterion ID: EX14A01 (For Pfizer use only)</p>	
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2.j Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administ ration or planned receipt througho ut the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.j Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX14A01	Initial Entry

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2.k				
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Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Exclusion Number: 16 Criterion Description: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation Criterion met?: NO Criterion ID: (For Pfizer use only): EX15A01	Initial Entry

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2.k Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.k Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Exclusion Number:	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

			Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles Criterion met?: NO Criterion ID: (For Pfizer use only): EX16A01	
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2.1 Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX16A01	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

2.m

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	<p>Data Entry:</p> <p>Exclusion Number: 22</p> <p>Criterion: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members</p> <p>Criterion ID: NO</p> <p>Criterion ID: EX21A01</p> <p>Use only: (For Pfizer use only):</p>	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

2.m Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.m Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: EX21A01	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.levissc

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
Jul-29-2020 16:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Jul/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jul-29-2020 16:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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.a

Date	Location	User	Value	Reason
Aug-03-2020 19:28:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Line/MH Number: Medical History appendicitis Term: Start Date: Jun/UNK/2004 Ongoing: NO End Date: Jun/UNK/2004	Changed Information
Jul-29-2020 16:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History appendicitis Term: Start Date: Jun/UNK/2004 Ongoing: NO End Date: Jun/UNK/2004	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f44\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:** 10011093**Generated By:** pfe.levisse**Form:** GENERAL MEDICAL HISTORY - 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

Aug-04-2020 11:17:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 1: Closed	Response satisfies query
Aug-03-2020 19:28:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-03-2020 19:28:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: appendicitis	Changed Information
Aug-03-2020 15:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora (pfe.signoj01)	Query 1: Opened	DM QUERY: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Jul-29-2020 16:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: appendicitis	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 16:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Jun/UNK/2004	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 16:52:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO End Date: Jun/UNK/2004	Initial Entry

1.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - 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-03-2020 19:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Line/MH Number: 2 Medical History Term: bilateral cataracts Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2020	Changed Information
Jul-29-2020 16:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: bilateral cataracts Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2020	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 11:18:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 1: Closed	Response satisfies query
Aug-03-2020 19:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-03-2020 19:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: bilateral cataracts	Changed Information
Aug-03-2020 15:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora (pfe.signoj01)	Query 1: Opened	DM QUERY: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Jul-29-2020 16:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: bilateral cataracts	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 16:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: UNK/UNK/2013	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - 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

I.b Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 16:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO End Date: UNK/UNK/2020	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-03-2020 19:28:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Line/MH Number: 3 Medical History Term: osteoarthritis Start Date: UNK/UNK/1994 Ongoing: YES	Changed Information
Jul-29-2020 16:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: osteoarthritis Start Date: UNK/UNK/1994 Ongoing: YES	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - 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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 11:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 1: Closed	Response satisfies query
Aug-03-2020 19:28:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-03-2020 19:28:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: osteoarthritis	Changed Information
Aug-03-2020 15:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora (pfe.signoj01)	Query 1: Opened	DM QUERY: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Jul-29-2020 16:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: osteoarthritis	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 16:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: UNK/UNK/1994	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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

I.c Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 16:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-03-2020 19:28:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Line/MH Numbe 4 r: Medical History pectus excavat Term: um Start Date: UNK/UNK/1 964 Ongoing: NO End Date: Jun/UNK/1 964	Changed Information
Jul-29-2020 16:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 4 r: Medical History pectus excavat Term: um Start Date: UNK/UNK/1 964 Ongoing: NO End Date: Jun/UNK/1 964	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1001

Subject No: 10011093

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - 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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 11:18:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 1: Closed	Response satisfies query
Aug-03-2020 19:28:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-03-2020 19:28:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: pectus excavatum	Changed Information
Aug-03-2020 15:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora (pfe.signoj01)	Query 1: Opened	DM QUERY: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Jul-29-2020 16:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: pectus excavatum	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 16:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: UNK/UNK/1964	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - 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

I.d Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 16:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO End Date: Jun/UNK/1964	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-08-2020 10:20:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gali Moritz (pfe.gmoritz)	Data Entry: Line/MH N 5 umber: Medical His Torn Anterior cru tory Term: ciate ligament Start Date: Dec/UNK/2000 Ongoing: NO End Date: Dec/UNK/2000	Transcription Error
Jul-29-2020 16:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 5 umber: Medical His Torn Anterior cru tory Term: ciate ligament Start Date: Dec/UNK/2000 Ongoing: NO End Date: UNK/UNK/2000	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - 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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Torn Anterior cruciate ligament	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 16:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Dec/UNK/2000	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-08-2020 10:20:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gali Moritz (pfe.gmoritz)	Data Entry: NO End Date: Dec/UNK/2000	Transcription Error
Jul-29-2020 16:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO End Date: UNK/UNK/2000	Initial Entry

I.f

Date	Location	User	Value	Reason
Jul-30-2020 09:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Line/MH Num 6 ber:	Transcription Error

090177e196ae2f44\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: 10011093

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - 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

			Medical History Term: Hernia, inguinal, left Start Date: UNK/UNK/1979 Ongoing: NO End Date: UNK/UNK/1979	
Jul-30-2020 09:45:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Line/MH Number: 6 Medical History Term: Hernia, inguinal, left Start Date: UNK/UNK/1979 Ongoing: NO End Date: UNK/UNK/1997	Transcription Error
Jul-30-2020 09:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Hernia, inguinal, left Start Date: UNK/UNK/1997 Ongoing: NO End Date: UNK/UNK/1997	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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.f Line/MH Number:

Date	Location	User	Value	Reason
Jul-30-2020 09:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 09:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Hernia, inguinal, left	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Jul-30-2020 09:45:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: UNK/UNK/1979	Transcription Error
Jul-30-2020 09:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: UNK/UNK/1997	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Jul-30-2020 09:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO End Date: UNK/UNK/1979	Transcription Error
Jul-30-2020 09:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO End Date: UNK/UNK/1997	Initial Entry

1.g

Date	Location	User	Value	Reason
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090177e196ae2f44\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: 10011093

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - 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

Jul-30-2020 09:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Hernia, inguinal, right Start Date: UNK/UNK/1997 Ongoing: NO End Date: UNK/UNK/1997	Initial Entry
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1.g Line/MH Number:

Date	Location	User	Value	Reason
Jul-30-2020 09:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 09:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Hernia, inguinal, right	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Jul-30-2020 09:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: UNK/UNK/1997	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Jul-30-2020 09:45:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: NO End Date: UNK/UNK/1997	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1001

Subject No: 10011093

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
Jul-29-2020 16:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Jul/29/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jul-29-2020 16:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 101.1	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jul-29-2020 16:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Jul-29-2020 16:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 189.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Jul-29-2020 16:56:31 (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
Jul-29-2020 16:56:31 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28.2	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1001

Subject No: 10011093

Generated By: pfe.levisse

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

Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Jul-29-2020 16:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Record Identifier: 1 : Temperature: 36.4 Temperature Unit C : Temperature Loc ORAL CAV ation:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jul-29-2020 16:56:31 (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
Jul-29-2020 16:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 36.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jul-29-2020 16:56:31 (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
Jul-29-2020 16:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.levissc

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
Jul-29-2020 16:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Jul/29/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jul-31-2020 16:10:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 220088	Transcription Error
Jul-29-2020 16:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry:	Initial Entry

090177e196ae2f44\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:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jul-29-2020 16:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-29-2020 16:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-29-2020 16:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-29-2020 16:43:44 (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.
Jul-29-2020 16:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: YES Date of Collection: Jul/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-29-2020 16:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Sample ID: BP773V	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 16:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	<u>Data Entry:</u> BP773V	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-29-2020 16:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	<u>Data Entry:</u> Sample ID: BP773W	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 16:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	<u>Data Entry:</u> BP773W	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-29-2020 16:44:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	<u>Data Entry:</u> Sample ID: BP773X	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 16:44:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	<u>Data Entry:</u> BP773X	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-29-2020 16:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	<u>Data Entry:</u> Sample ID: BMR2HF	Initial Entry

090177e196ae2f44\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: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

5.d Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 16:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: BMR2HF	Initial Entry

5.e

Date	Location	User	Value	Reason
Jul-29-2020 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Sample ID: BMR2HD	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 16:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: BMR2HD	Initial Entry

090177e196ae2f44\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:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jul-29-2020 16:56:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-29-2020 16:56:54 (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
Jul-29-2020 16:57:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-29-2020 16:56:54 (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.
Jul-29-2020 16:56:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: YES Date of Collection: Jul/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-29-2020 16:57:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Sample ID: BP7736	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

5.a Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 16:57:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: BP7736	Initial Entry

090177e196ae2f44\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: 10011093

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
Jul-29-2020 16:57:19 (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
Jul-29-2020 16:57:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jul-29-2020 16:57:19 (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
Jul-29-2020 16:57:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Jul/29/2020 13:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jul-29-2020 16:57:19 (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
Jul-29-2020 16:57:19 (UTC-05:00) Eastern	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: LEFT	Initial Entry

090177e196ae2f44\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: 10011093

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

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Jul-29-2020 16:57:19 (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
Jul-29-2020 16:57:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:57:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: YES	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.levissc

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-24-2020 09:22:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Closed	Response satisfies query
Aug-21-2020 10:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Query 1: Answered	Please see https://trialmax.crfhealth.net/manager-6.0.0/A-1426-0086/patientindex.faces?siteid=2706343000000000000 Portal: C4591001-post-12-july-2020
Aug-21-2020 02:38:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Opened	ClinQuery: It appears subject was given a reactogenicity diary, however, there is no data collected for this subject in TM. Please can you review and update if subject was given an e-diary? Else clarify
Jul-29-2020 16:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011093

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-19-2020 14:10:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Aug/19/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 17-Jul-2020 21:54**Site No:** 1001**Subject No:** 10011093**Generated By:** pfe.levissc**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - 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[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (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-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the las O t day the Subject Diary w as completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (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-19-2020 15:46:22 (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-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: FA	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

				TI GU E
				Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO

2.b Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (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-19-2020 15:46:22 (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-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

2.c Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: 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-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (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-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

2.e

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s ymptoms present on the last day the Subject Diar y was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (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-19-2020 15:46:22 (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-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic s ymptoms present on the l ast day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

2.f Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (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-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste NO mic symptoms pres ent on the last day t he Subject Diary w as completed?:	Initial Entry

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NEW OR WORSENER MUSC LE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (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-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Symptom:: NEW O R WORS ENED J OINT PA IN Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:	Initial Entry

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (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-19-2020 15:46:22 (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-19-2020 15:46:22 (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-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

5.a Injection Site Reaction:

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary wa s completed?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

Aug-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-19-2020 15:46:22 (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-19-2020 15:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1001

Subject No: 10011093

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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1. Date:

Date	Location	User	Value	Reason
Aug-19-2020 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Aug/19/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-19-2020 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Record Identifier:: 1 Temperature: 36.3 Temperature Unit: C Temperature Location:: EAR	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-19-2020 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Aug-19-2020 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: 36.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: C	Initial Entry

2.a Temperature Location:

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1001

Subject No: 10011093

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

Date	Location	User	Value	Reason
Aug-19-2020 14:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: EAR	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-19-2020 14:13:07 (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-19-2020 14:13:07 (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-19-2020 15:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 14:13:07 (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-19-2020 14:13:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 15:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Sample ID: BP76H8	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

5.a Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 15:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: BP76H8	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011093

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-19-2020 14:11:58 (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-19-2020 14:11:58 (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-19-2020 14:11:58 (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-25-2020 07:07:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sanjay Mishra (pfe.mishrs01)	Query 1: Clo sed	Response satisfies query
Aug-24-2020 13:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Query 1: An swere d	Changed data per query
Aug-22-2020 04:08:58 (UTC-05:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Op ened	Subject has reported with Severe

090177e196ae2f44\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: 10011093

Generated By: pfe.levisse

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

Eastern Time (US & Canada)				symptoms/reactions on '2020-08-20'. Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate. "[newtod07 SDQ=917]"
Aug-19-2020 14:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry : Aug/19/2020 13:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-19-2020 14:11:58 (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-19-2020 14:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-19-2020 14:11:58	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	INTRAMUSCULAR	
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-19-2020 14:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 14:11:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011093

Generated By: pfe.levisse

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-21-2020 13:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Sep/21/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:54**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Symptom:: FE VE R Were fever or systemic sym N ptoms present on the last d O ay the Subject Diary was co mpleted?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	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-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Symptom:: FA	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

			TI GU E NO	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.b Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	<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-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	<u>Data Entry:</u> <u>Symptom::</u> HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: 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-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	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-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.e

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	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
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?: NO	Initial Entry

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	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
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Symptom:: NEW OR WORSEN ED MUS CLE PAI N Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NEW OR WORSENE D MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Symptom: NEW OR WORSE NEEDED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	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-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (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-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

5.b

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactio ns present on the last day the Subject Diary was co mpleted?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	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-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Injection Site Reaction PAIN A :: T INJE CTION SITE Were injection site rea NO ctions present on the la st day the Subject Diar y was completed?:	Initial Entry

090177e196ae2f44\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: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	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-21-2020 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: NO	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-21-2020 13:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 13:54:47 (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-21-2020 17:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 13:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 13:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-21-2020 17:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Sample ID: BMR2XM	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 17:15:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: BMR2XM	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-21-2020 17:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Sample ID: BMR2XW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 17:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: BMR2XW	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-21-2020 17:17:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: Sample ID: BP76RB	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 17:17:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mahnoor Ali (pfe.mali1)	Data Entry: BP76RB	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1001

Subject No: 10011093

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-10-2021 13:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Feb/10/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Queries, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

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
Feb-10-2021 13:41:22 (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-10-2021 13:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-10-2021 04:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloi (pfe moloim)	Query 3: Reissued:Opened	DM: Since no sample was not collected , please provide reason on appropriate field.
Mar-09-2021 16:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Query 3: Answered	Convalescent visit and visit 4 were done on the same day. Per protocol only needs to be documented under convalescent visit.
Mar-09-2021 14:12:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katerina Trpeski (pfe.TRPESK)	Query 3: Reissued:Opened	DM: Please place the query response under "If no sample was collected or sample was not collected according to protocol, please provide reason:" Thank you.

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** V4_MONTH6_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Queries, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

Mar-09-2021 11:06:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Query 3: Answered	Data captures under convalescent visit since visits were done on the same day.
Mar-09-2021 11:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Mar-09-2021 11:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Mar-09-2021 11:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-09-2021 11:04:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Mar-09-2021 11:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Mar-09-2021 11:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: NO	data corrected
Feb-10-2021 13:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 13:41:22	ACV0PFEINFP6000	auto query	Query 1: Candidate	'Sample Collected?'

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Queries, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-10-2021 13:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: YES Date of Collection: Feb/10/2021	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Mar-09-2021 11:04:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry:	data correction
Feb-10-2021 13:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: sample is captured in the convalescent visit	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-09-2021 11:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID: Not Applicable	Initial Entry
Feb-10-2021 13:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID:	sample is captured in the convalescent visit
Feb-10-2021 13:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID: BNW7SL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 11:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** V4_MONTH6_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Queries, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-10-2021 13:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry:	sample is captured in the convalescent visit
Feb-10-2021 13:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: BNW7SL	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-09-2021 11:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID: Not Applicable	Initial Entry
Mar-09-2021 11:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID:	data corrected per protocol
Feb-10-2021 13:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID: BNW7SK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 11:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry
Mar-09-2021 11:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry:	data corrected per protocol
Feb-10-2021 13:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: BNW7SK	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-09-2021 11:05:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Queries, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

Mar-09-2021 11:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID:	data corrected per protocol
Feb-10-2021 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID: BP27G7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 11:05:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry
Mar-09-2021 11:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry:	data corrected per protocol
Feb-10-2021 13:43:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: BP27G7	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/13/2021**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)***1. Date of Visit***

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-26-2021 13:42:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 13:42:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-26-2021 13:42:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-26-2021 13:42:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/13/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-26-2021 13:42:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Jan/13/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/13/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/11/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry
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4.b

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Symptom Present: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Symptom NEW OR INCREASED	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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			s: ED MUSCLE PAIN Symptom YES Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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4.g

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Symptom NEW OR INCREASE S: D SORE THROAT Symptom NO Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-26-2021 13:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Jan-26-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-26-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/13/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-26-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-26-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-26-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-26-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Feb-03-2021 14:04:18 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)				
Jan-26-2021 13:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Trade Name is Other, however Trade Name Other, Specify is not completed. Please update.
Jan-26-2021 13:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-26-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Feb-15-2021 02:19:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Feb-14-2021 17:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	data entered
Feb-14-2021 17:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NALT Unknown	data entered
Feb-05-2021	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD	Query 1:	As per CRF

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

02:43:23 (UTC-05:00) Eastern Time (US & Canada)		(pfe.PFESDQ_PROD)	Opened	CR, If trade name is not known. Please update NALT Unknown in the specified field, Thank you. "[lv04 SDQ=118452]"
Feb-03-2021 14:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: N/A	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Jan/13/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
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:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-26-2021 13:42:57 (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-26-2021 13:42:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-26-2021 13:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 13:42:57 (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-26-2021 13:42:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES Date of Collection: Jan/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-26-2021 13:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sample ID: CV07749	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-26-2021 13:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: CV07749	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Jan/13/2021

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: 10011093

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-26-2021 13:51:32 (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-26-2021 13:51:32 (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-26-2021 13:51:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Jan-26-2021 13:51:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: not needed per protocol	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/13/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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1.a

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/13/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.c

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO :	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/13/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

1.d

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/13/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/13/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

Jan-26-2021 13:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

Jan-26-2021 13:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-26-2021 13:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jan-26-2021 13:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 13:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: 2	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-26-2021 13:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-26-2021 13:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-26-2021 13:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 13:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

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Form Version: 17-Jul-2020 21:53

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Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

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			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

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Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Applicable	Initial Entry

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

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Date	Location	User	Value	Reason
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Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
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5.g

Date	Location	User	Value	Reason
Jan-26-2021 13:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

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Date	Location	User	Value	Reason
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5.g Test:

Date	Location	User	Value	Reason
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Generated By: pfe.levissc

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

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			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.b

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Date	Location	User	Value	Reason
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5.b Test:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

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			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

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5.d

Date	Location	User	Value	Reason
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5.h Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u>	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

Time (US & Canada)			Sponsor-Defined Identifier:	Not Applicable	
			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range:	Not Applicable	

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-26-2021 13:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Jan/13/2021**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-26-2021 13:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-26-2021 13:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in re Not App spirations/minute: licable Heart Rate in beats/mi Not App nute: licable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-26-2021 13:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-26-2021 13:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Jan/13/2021

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-26-2021 13:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-26-2021 13:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-26-2021 13:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date:

Date	Location	User	Value	Reason
Jan-26-2021 13:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-26-2021 13:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Record Identifier: Not Applicabl : e Oxygen Saturatio Not Applicabl n: e	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-26-2021 13:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-26-2021 13:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-26-2021 13:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Jan-26-2021 13:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-26-2021 13:45:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Jan/13/2021**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1001**Site Name:** (1001) NYU Langone Health**Subject No:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

6. Ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 13:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-26-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-26-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-26-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-26-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Not Done	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/10/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 13:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Feb/10/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-10-2021 13:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: COVID_A1	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/10/2021

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: 10011093

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
Feb-10-2021 13:45:17 (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-10-2021 13:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-09-2021 09:46:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Mar-09-2021 09:40:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Mar-09-2021 09:40:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-09-2021 09:40:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: YES Date of Collection: Feb/10/2021	data corrected
Mar-09-2021 09:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001 Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/10/2021 Form Version: 22-Apr-2020 21:03 Site No: 1001 Subject No: 10011093 Generated By: pfe.levissc					Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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				
					according to protocol, please provide reason' is missing. Please review and update as appropriate.				
Feb-23-2021 08:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloji (pfe moloim)	Query 2: Reissued:Opened		DM: Per CCG, in case a Conva visit occurs at the same time as V4, sample collection date and barcodes should be recorded on Conva visit. Please consider moving data from V4 to Conva form.				
Feb-22-2021 14:18:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered		Answer Auto Query				
Feb-22-2021 14:18:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: NO		data updated as requested				
Feb-14-2021 22:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 2: Reissued:Opened		DM : Thanks for response. If V4 and COV CONVA occurred on same day. Please review and update the IMMUNOGENICITY data in COV CONVA visit. And Sample collected = No and provide reason on CRF at visit 4. Else, clarify.				
Feb-14-2021 17:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Query 2: Answered		Same samples as V4. convalescent visits and Visit 4 occurred in same day. How do you want to me enter this information in this section?				

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit on Feb/10/2021**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:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-11-2021 06:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe nairr29)	Query 2: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-10-2021 13:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-10-2021 13:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 13:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-10-2021 13:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: YES Date of Collection: Feb/10/2021	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Mar-09-2021 09:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-09-2021 09:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry:	data error
Mar-09-2021 09:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/10/2021**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:** 10011093**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

				removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Mar-09-2021 09:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: BNW7SL	Initial Entry
Mar-09-2021 09:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry:	data corrected
Feb-10-2021 13:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-10-2021 13:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Same samples as V4. Both visits occurred in same day.	space removed
Feb-10-2021 13:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Feb-10-2021 13:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Same samples as V4. Both visits occurred in same day.	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-09-2021 09:46:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID: BP27G7	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/10/2021

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: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

Time (US & Canada)				
Mar-09-2021 09:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID:	Initial Entry
Feb-10-2021 13:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID: Not Applicable	Initial Entry
Feb-10-2021 13:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID:	sample is captured in the convalescent visit
Feb-10-2021 13:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID: BP27G7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 09:46:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: BP27G7	Initial Entry
Mar-09-2021 09:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry:	Initial Entry
Feb-10-2021 13:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Not Applicable	Initial Entry
Feb-10-2021 13:51:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry:	sample is captured in the convalescent visit
Feb-10-2021 13:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: BP27G7	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-09-2021 09:47:39 (UTC-05:00) Eastern	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID: BNW7SK	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/10/2021

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: 10011093

Subject Initials: ---

Generated By: pfe.lewiss

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

Time (US & Canada)				
Mar-09-2021 09:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID:	Initial Entry
Feb-10-2021 13:52:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID: Not Applicable	Initial Entry
Feb-10-2021 13:52:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID:	sample is captured in the convalescent visit
Feb-10-2021 13:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID: BNW7SK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 09:47:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: BNW7SK	Initial Entry
Mar-09-2021 09:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry:	Initial Entry
Feb-10-2021 13:52:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Not Applicable	Initial Entry
Feb-10-2021 13:52:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry:	sample is captured in the convalescent visit
Feb-10-2021 13:46:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: BNW7SK	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-09-2021 09:47:49 (UTC-05:00) Eastern	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID: BNW7SL	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/10/2021

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: 10011093

Subject Initials: ---

Generated By: pfe.lewissc

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

Time (US & Canada)				
Mar-09-2021 09:42:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID:	Initial Entry
Feb-10-2021 13:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID: Not Applicable	Initial Entry
Feb-10-2021 13:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID:	sample is captured in the convalescent visit
Feb-10-2021 13:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Sample ID: BNW7SL	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 09:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: BNW7SL	Initial Entry
Mar-09-2021 09:42:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry:	Initial Entry
Feb-10-2021 13:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Not Applicable	Initial Entry
Feb-10-2021 13:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry:	sample is captured in the convalescent visit
Feb-10-2021 13:46:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: BNW7SL	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/21/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

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
Aug-24-2020 13:28:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: Aug/21/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/21/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Assessments

Date	Location	User	Value	Reason
Aug-24-2020 13:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-24-2020 13:30:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Aug-24-2020 13:30:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Aug/21/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1001**Subject No:** 10011093**Generated By:** pfe.levissc**Form:** CONTACT OUTCOME - UNPLANNED - 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[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Aug-24-2020 13:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Aug-27-2020 09:39:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Closed	Response satisfies query
Aug-26-2020 10:34:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-26-2020 10:34:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Akeem Moore (pfe.amoore1)	Data Entry: YES Date of Contact: Aug/21/2020 Contact Outcome: VISIT NOT REQUIRED, I NVESTIGATOR DECISIO N	Transcription Error
Aug-25-2020 20:19:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Opened	ClinQuery: UNPL states that contact was not made, however, the comments indicate that the SUB-I called the subject. please review and update as appropriate. thanks
Aug-24-2020 13:31:42	ACV0PFEINFP6000	Akeem Moore	Data Entry:	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Aug/21/2020

Form Version: 22-Apr-2020 21:04

Site No: 1001

Subject No: 10011093

Generated By: pfe.lewissc

Form: CONTACT OUTCOME - UNPLANNED - 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

(UTC-05:00) Eastern Time (US & Canada)

(pfe.amoore1)

NO

If No, why?

After telehealth call Sub-I de
termined it was not needed.

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

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
Sep-22-2020 08:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Sep/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-22-2020 08:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-22-2020 08:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.lewissc

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
Jan-14-2021 11:47:13 (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: 10011093

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
Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-14-2021 11:47:13 (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-10-2021 11:28:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Feb-10-2021 09:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Updated as requested
Feb-10-2021 09:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Chest Pain	Updated as requested
Feb-02-2021 12:33:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical SAE event term updated to 'Chest Pain'; however, event term on AE CRF remains catheterization procedure. Please update event term here to the reported SAE term.
Feb-02-2021 12:31:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	updating query

090177e196ae2f44\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: 10011093

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

Jan-27-2021 18:18:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Covid Illness visit recorded
Jan-27-2021 18:17:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Covid Illness visit recorded
Jan-22-2021 22:45:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical Referring to the SAE report which includes the catheterization procedure, patient reported symptoms of non-radiating chest pain, dyspnea, weakness, chills, sweats.
Jan-20-2021 21:02:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 3: Reissued:Opened	Clin: if telehealth visit was not done, please complete the potential COVID-19 Illness CRF forms with all information available and a NASAL SWAB collected if the last symptoms resolved less than 4 day ago
Jan-20-2021 21:02:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 2: Reissued:Opened	Clin: CHILLS, DYSPNEA on 10Jan2021 should have please triggered a COVID-19 Visit irrespective of perceived etiology or clinical significance and captured also on the SOD form.
Jan-20-2021 14:49:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Query 1: Answered	What terms would better qualify for this?

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1001

Subject No: 10011093

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

Jan-20-2021 11:12:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	CLINICAL please change the event term for both the AE and SAE (matching event term) from a procedure event term, to a clinical event term
Jan-19-2021 17:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	to match term with SAE report
Jan-19-2021 17:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	to match term with SAE report
Jan-19-2021 17:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	to match term with SAE report
Jan-19-2021 17:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa Zhao (pfe.lzhao)	Data Entry: left heart catheterization	to match term with SAE report
Jan-18-2021 15:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 3: Opened	Clin: if telehealth visit was not done, please complete the COVID-19 Illness CRF forms with all information available and a NASAL SWAB collected if the last symptoms resolved less than 4 day ago
Jan-18-2021 15:22:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 2: Opened	Clin: It was stated in the AER# 2021030659 - subject experienced CHILLS, DYSYPNEA on 10Jan2021 that should have please triggered a COVID-19 Visit

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1001

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Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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				irrespective of perceived etiology or clinical significance and captured also on the SOD form.
Jan-16-2021 21:19:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL SAE event is angina; however, SAE report event is Lt heart cath with possible stent. Please avoid use of a procedure term in reporting adverse events; review term and harmonize reporting
Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: angina	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-02-2021 12:32:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	SAE start date updated to 10Jan21
Jan-27-2021 18:21:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Event start date is 10Jan21; however, SAE report has original start date of 13Jan21. Please submit a SAE followup to update the SAE start date in that location as well.
Jan-27-2021 18:15:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query

090177e196ae2f44\Final\Final On: 01-Apr-2021 03:38 (GMT)

Header Text: c4591001

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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Subject Initials: ---

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

Jan-26-2021 13:53:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-26-2021 13:53:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gali Moritz (pfe.gmoritz)	Data Entry: Jan/10/2021 12:09	New Information
Jan-22-2021 22:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical Thank you, however was there a change; event start date is 13Jan21 / symptoms start date is 10Jan21.
Jan-20-2021 14:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Query 1: Answered	data corrected
Jan-20-2021 11:10:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical As noted, in Vaccine study, SAE start date is day event starts; not day it meets serious criteria (ie date Hospitalized). If SAE event began as non-serious, record the onset date as the date the non-serious event began.
Jan-19-2021 17:59:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa Zhao (pfe.lzhao)	Query 1: Answered	admission to hospital was on 13 Jan 2021, data entry is accurate
Jan-18-2021 08:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Event start date is 13Jan; however, SAE report states Sx including non-radiating CP started 10Jan. In Vaccine study, SAE start date is day event starts; not day it meets serious

090177e196ae2f44\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: 10011093

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

				criteria (item 11 in vaccine SAE instruct); please review start date
Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/13/2021 12:09	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-25-2021 22:16:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-24-2021 11:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Query 1: Answered	SAE follow up has been faxed today
Feb-22-2021 12:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical Event end date is 1/13; however, SAE report has no event end date. Please submit a SAE followup with Event End Date reported.
Feb-10-2021 11:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	data update per source document
Feb-10-2021 11:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO End Date Time: Jan/15/2021 UNK:UNK	data update per source document
Jan-27-2021 18:21:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Event end date is 1/13; however, SAE report has no event end date. Please submit a SAE followup with

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1001**Subject No:** 10011093**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

				Event End Date reported.
Jan-20-2021 14:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO End Date Time: Jan/13/2021 UNK:UNK	data correction
Jan-15-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO End Date Time: Jan/14/2021 UNK:UNK	new information
Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-14-2021 11:47:13 (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-02-2021 17:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	COVID test during hosp was negative
Jan-20-2021 11:16:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Jan-20-2021 11:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical COVID test status (yes/no) during Hosp was not

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1001**Subject No:** 10011093**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

				reported in the SAE. Please submit a follow-up SAE form [#2021030659] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-20-2021 07:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Jan-19-2021 18:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	to reconcile with SAE report
Jan-19-2021 18:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	to reconcile with SAE report
Jan-19-2021 18:01:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lisa Zhao (pfe.lzhao)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p>	to reconcile with SAE report

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			Is this serious event life threatening? NO Other medically important serious event NO	
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Generated By: pfe.lewissc

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Form Status: Data Complete, Frozen

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Jan-19-2021 17:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE left heart catheterization: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-18-2021 08:23:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical SAE serious criteria are Hosp and Med Important; however, SAE report serious criterion is Hosp. Please review, harmonize reporting, and update in the appropriate location.
Jan-18-2021 08:21:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021030659] to document if COVID testing was performed (YES/NO or info not available) and if

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				yes, the date and results.
Jan-14-2021 23:50:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE angina: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p>	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-15-2021 21:00:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 2: Closed	Response satisfies query
Feb-10-2021 11:48:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Query 2: Answered	not study related. Please clarify your request after reviewing the full AE page
Feb-02-2021 20:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 2: Opened	ClinQuery: left heart catheterization: question 9 states this is related to a cardiac ischemia, however, this is not listed in the AE log or the medhx. Please review/update as appropriate. Thanks
Jan-20-2021 11:09:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-20-2021 08:17:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	data clarification
Jan-20-2021 08:17:31 (UTC-05:00) Eastern	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NOT RELATED	data clarification

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Time (US & Canada)			If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> cardiac ischemia	
Jan-16-2021 21:22:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Other cause for Angina event would not be angina; please enter underlying cardiac diagnosis
Jan-14-2021 12:02:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> angina	per query request
Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-14-2021 11:47:13 (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
Jan-15-2021 13:11:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES	new information

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Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 02:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 5: Closed	Response satisfies query
Feb-24-2021 14:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 5: Reissued: Candidate	Pending SDB update
Feb-24-2021 11:03:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Query 5: Answered	SAE follow up form has been faxed today.
Feb-16-2021 22:04:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 5: Opened	SAE RECON:AER#2021030659 .outcome was updated to RECOVERED/RESOLVED on AE CRF while reported as Recovering/Resolving in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-02-2021 08:34:39 (UTC-05:00)	ACV0PFEINFP6000	Malerato Moloi (pfe.moloim)	Query 3: Closed	Response satisfies query

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Generated By: pfe.lewissc

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Eastern Time (US & Canada)				
Feb-01-2021 15:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Answer Auto Query
Feb-01-2021 15:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Jan-22-2021 00:35:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 3: Reissued: Opened	DM: Per CRF, outcome is entered as 'RECOVERING/RESOLVING' however AE End Date/Time is also entered which indicate AE is resolved. Kindly verify if this AE is resolved. If yes then update outcome on this page as needed. Else clarify.
Jan-21-2021 04:58:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 4: Closed	Response satisfies query
Jan-21-2021 04:16:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	Response satisfies query
Jan-20-2021 14:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Query 4: Answered	Data updated. Please let me know what you are looking for.
Jan-20-2021 14:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE left heart catheterization: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.

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Jan-20-2021 08:35:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Query 3: Answered	Subject was discharged from the hospital. Our clinician will follow up with the participant.
Jan-20-2021 08:29:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE left heart catheterization: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Jan-20-2021 08:29:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Participant has been discharged from the hospital. Our clinician will follow up with the subject.
Jan-20-2021 08:29:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: RECOVERING/RESOLVING	Participant has been discharged from the hospital. Our clinician will follow up with the subject.
Jan-20-2021 07:37:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe. quitor)	Query 2: Opened	SAE RECON:AER#2021030659,outcome was reported as RECOVERING/RESOLVING to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Jan-15-2021 13:11:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-15-2021 13:11:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: RECOVERED/RESOLVED	new information

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Jan-15-2021 13:10:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE angina: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NOT RECOVERE D/NOT RESOLV ED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-14-2021 11:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-20-2021 07:35:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotr)	Data Entry: 2021030659	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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Date	Location	User	Value	Reason
Sep-25-2020 13:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1001

Site Name: (1001) NYU Langone Health

Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Sep-25-2020 13:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Sep-25-2020 13:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Sep-25-2020 13:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Sep-25-2020 13:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> flu vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Sep-25-2020 13:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	<u>Data Entry:</u> Sep/14/2020	Initial Entry

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Visit: Potential ReVax Initial Contact -
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Form: DATE OF VISIT - eCRF Audit Trail History

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Site No: 1001

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Subject No: 10011093

Subject Initials: ---

Generated By: pfe.levissc

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-21-2021 16:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/21/2021	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1001

Subject No: 10011093

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Jan-28-2021 11:54:18 (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 and NOT confirmed to have received only placebo at V accination 1/2	data correction
Jan-21-2021 16:09:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe nria)	Data Entry: Participant is NOT willing to retur n for Vaccination 3 OR otherwise not eligible	Initial Entry

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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1001

Subject No: 10011093

Generated By: pfe.lewissc

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-21-2021 16:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: Jan/21/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-21-2021 16:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nazia Ria (pfe.nria)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.levisse

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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1. Subject Status

Date	Location	User	Value	Reason
Sep-22-2020 08:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jul-29-2020 16:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jul-29-2020 16:43:27 (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
Jan-27-2021 01:43:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	visit reported
Jan-26-2021 13:52:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gali Moritz (pfe.gmoritz)	Query 1: Answered	Illness visit is reported in Inform for 13Jan2021
Jan-21-2021 14:27:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 12JAN2021. But there is no COVID Illness visit reported in the database. Please clarify.
Sep-22-2020 08:55:47	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2f44\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: 10011093

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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Sep/21/2020	
Jul-29-2020 16:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/29/2020	Initial Entry
Jul-29-2020 16:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/29/2020	Initial Entry

090177e196ae2f44\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: 10011093

Generated By: pfe.levisse

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
Aug-25-2020 12:52:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sara Hyman (pfe.shyman)	Data Entry: Click Here to Enable	Initial Entry