

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.lewissc

**Form:** COHORT\_SELECTION

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

1.	Select appropriate response - Protocol version	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:** 1003

**Subject No:** 10031113

**Generated By:** pfe.lewissc

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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/30/2020
----	--------------	--

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** DEMOGRAPHY

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10031113]
2.	Birth Date:	(b) (6) /1946
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:	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jul/30/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisc

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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**

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

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.l	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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



<b>Header Text:</b> c4591001	<b>Form:</b> DISPOSITION - SCREENING
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031113	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levisse	

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Jul/30/2020
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:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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:	[Osteoarthritis]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Interstitial Lung Disease]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.leviscc

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Jul/30/2020
2.	Weight:	[158.0]
3.	Unit:	LB
4.	Height:	[71.0]
5.	Unit:	in
6.	Body Mass Index:	[22.0]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.3]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> RANDOMIZATION
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031113	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levissc	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Jul/30/2020
2.	Randomization Number:	[220530]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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/30/2020
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	[BGJWDX]
5.b	Sample ID	[BGJWDY]
5.c	Sample ID	[BGJWDZ]
5.d	Sample ID	[BKDYVG]
5.e	Sample ID	[BKDYVH]

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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/30/2020
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	[BGJWDB]
-----	-----------	----------

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1003  
**Subject No:** 10031113  
**Generated By:** pfe.levissc

**Form:** VACCINATION  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1003) Rochester Regional HealthRochester General Hospital  
**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/30/2020 13:55
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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> REACTOGENICITY DIARY
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 06-Jul-2020 21:53	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031113	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levisc	

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/20/2020
2.	Erroneous Visit	

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/20/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.4]
	Unit:	F
	Temperature Location:	FOREHEAD

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP57HR]
-----	-----------	----------

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisc

**Form:** VACCINATION

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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/20/2020 13:04
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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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	[BPYL6L]
5.b	Sample ID	[BNWKBS]
5.c	Sample ID	[BNWKBT]

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/26/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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:	[same as convalescent blood]

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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	[ ]
----	-----------	-----

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Oct/15/2020

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/15/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Oct/15/2020

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

**Signs and Symptoms**

1.	Date of Assessment:	Oct/15/2020
2.	Date of First Symptom Started:	Oct/14/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Dec/4/2020

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	YES
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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Oct/15/2020

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**Symptoms - Other**

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.leviscc

**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.	Oct/14/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Oct/15/2020

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Microbiology Specimen**

1.	Actual Date of Collection:	Oct/14/2020
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:	CEPHEID XPRT XPRESS SARS-COV-2 TEST
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Oct/15/2020

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[swab obtained on site]

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Oct/15/2020

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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: Oct/15/2020
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	[BPYL9X]
-----	-----------	----------

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Oct/15/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**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?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO
----	--	--



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Oct/14/2020	NO Discharge Date:  Oct/16/2020	<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS  
on Oct/15/2020

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS	
2.	Hospitalization Term:	HOSPITAL	
3.	Admission Date:	Oct/14/2020	
4.	Ongoing?	NO Discharge Date: Oct/16/2020	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Oct/15/2020

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

**Form Status:** Incomplete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

### Respiratory Treatment

1.	What is the treatment Identifier?	[ ]	<a href="#">Comments</a>
2.	Concomitant Non-drug Treatment Pre-specified:		<a href="#">Comments</a>
3.	Treatment:		<a href="#">Comments</a>
4.	Treatment:	[ ]	<a href="#">Comments</a>
5.	Start Date:	//	<a href="#">Comments</a>
6.	Ongoing?		<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Oct/15/2020

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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?	YES Respiratory Illness Diagnosis: [severe sepsis]  Date of Diagnosis: Oct/14/2020
3.	Toxicity Grade:	4

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Category of Clinical Event :	Subcategory of Clinical Event t	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Oct/15/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 17-Jul-2020 21:53

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

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.	CLINICAL CHEMISTRY	Rochester General Hospital Lab 1425 Portland Ave. Rochester NY 14621	Oct/14/2020	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					329	C Reactive Protein_PX329	14.1	
					30	Alanine Aminotransferase_PX30	24	
					28	Aspartate Aminotransferase_PX28	40	
					35	Alkaline Phosphatase_PX35	96	
					21	Bilirubin_PX21	.9	
					47	Blood Urea Nitrogen_PX47	16	
					48	Creatinine_PX48	.9	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Oct/15/2020

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Rochester General Hospital Lab 1425 Portland Ave. Rochester NY 14621]
3.	Collection Date:	Oct/14/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[14.1]
	Not Done:	
	LNMT	Low [0.0] High [10.0] Unit mg/L
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[24]
	Not Done:	
	LNMT	Low [10] High [49] Unit U/L

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Oct/15/2020

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[40]
	Not Done:	
	LNMT	Low [7] High [37] Unit U/L

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[96]
	Not Done:	
	LNMT	Low [46] High [116] Unit U/L

5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[.9]
	Not Done:	
	LNMT	Low [.3] High [1.2] Unit mg/dL

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Oct/15/2020

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[16]
	Not Done:	
	LNMT	Low [8] High [20] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[.9]
	Not Done:	
	LNMT	Low [.7] High [1.2] Unit mg/dL

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 17-Jul-2020 21:53

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
1.	HEMATOLOGY	Rochester General Hospital 142 5 Portland Ave Rochester NY 1 4621	Oct/14/2 020	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					1	Hemoglobin_PX1	16.1	
					2	Hematocrit_PX2	48	
					3	Erythrocytes_PX3	4.82	
					5	Platelets_PX5	179	
					7	Leukocytes_PX7	4.5	
					608	Neutrophils_PX608	85%	
					609	Eosinophils_PX609	0%	
					612	Monocytes_PX612	0%	
					610	Basophils_PX610	0%	
					611	Lymphocytes_PX611	.2	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/15/2020

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Rochester General Hospital 1425 Portland Ave Rochester NY 14621]
3.	Collection Date:	Oct/14/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[16.1]
	Not Done:	
	LNMT	Low [13] High [18] Unit g/dL

5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[48]
	Not Done:	
	LNMT	Low [40] High [52] Unit %

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/15/2020

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.82]
	Not Done:	
	LNMT	Low [4.40] High [6.20] Unit /uL

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[179]
	Not Done:	
	LNMT	Low [150] High [450] Unit 10^3/uL

5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[4.5]
	Not Done:	
	LNMT	Low [4.0] High [11.0] Unit 10^3/uL

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Oct/15/2020

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[85%]
	Not Done:	
	LNMT	Low [45] High [75] Unit %

5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0%]
	Not Done:	
	LNMT	Low [0] High [5] Unit %

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0%]
	Not Done:	
	LNMT	Low [0] High [15] Unit %

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/15/2020

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0%]
	Not Done:	
	LNMT	Low [0] High [3] Unit %

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[.2]
	Not Done:	
	LNMT	Low [1.0] High [4.8] Unit 10 <sup>3</sup> /uL

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date:	Vital Signs Details			Form Instance
1.	Oct/14/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	80	53	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Oct/15/2020

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Vital Signs**

1.	Date:	Oct/14/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[80]
	Diastolic:	[53]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[103]

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date:	Vital Signs Details		Form Instance
1.	Oct/14/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	98.0	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Oct/15/2020

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Vital Signs**

1.	Date:	Oct/14/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[98.0]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Oct/15/2020 23:51	98	Unknown	<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Oct/15/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Oxygenation Parameters**

1.	Date Time of Assessment:	Oct/15/2020 23:51	
2.	Arterial Blood Gases PaO2 (mmHg):	[98]	
3.	FiO2 (Fraction of Inhaled Oxygen):	Unknown [ ]	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Oct/15/2020

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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.	Oct/14/2020	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i>  increased retrocardiac airspace opacity of left lower zone, concerning for pneumonia.	<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING  
on Oct/15/2020

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Imaging**

1.	Date of Assessment:	Oct/14/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	ABNORMAL If abnormal, specify findings: [increased retrocardiac airspace opacity of left lower zone, concerning for pneumonia.]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - 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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - 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, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
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**

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - 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, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.a

Symptoms - Other Text:

[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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. DELETED	Jan/11/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Jan/13/2021

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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

**Microbiology Specimen**

1.	Actual Date of Collection:	<del>Jan/11/2021</del>
2.	Specimen Type:	<del>SWABBED MATERIAL</del>
3.	Specimen Collection Location:	<del>NASOPHARYNX</del>
4.	Assay Code and Description:	<del>SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2</del>
5.	Device Type:	<del>SARS-COV-2 DIAGNOSTIC TEST</del>
6.	Trade Name:	<del>CEPHEID XPERT XPRESS SARS-COV-2 TEST</del>
7.	Test Result:	<del>NEGATIVE</del>
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - 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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - 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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Jan/13/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**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?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO
----	--	--

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Jan/11/2021	NO Discharge Date:  Jan/13/2021	<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS  
on Jan/13/2021

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Jan/11/2021
4.	Ongoing?	NO Discharge Date: Jan/13/2021

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Jan/13/2021

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

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Respiratory Treatment**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Category of Clinical Event :	Subcategory of Clinical Event t	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Jan/13/2021

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Jan/13/2021

**Form Version:** 17-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Lab Chemistry Details**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

**Form Version:** 17-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Laboratory Data Hematology**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - COVID

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date:	Vital Signs Details			Form Instance
1.		<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Jan/13/2021

**Form Version:** 17-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date:	Vital Signs Details		Form Instance
1.		<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Jan/13/2021

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

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Jan/13/2021

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

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Jan/13/2021

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** IMAGING

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** IMAGING  
on Jan/13/2021

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

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/18/2020

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

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/18/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/18/2020

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisc

**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: Nov/18/2020
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	[BPYLC7]
5.b	Sample ID	[BNWKMP]
5.c	Sample ID	[BNWKKP]

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Feb/26/2021

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

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/26/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_B1
----	-------------------------	----------

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Feb/26/2021

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[low draw]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYLTLD]
5.b	Sample ID	[BVR36N]

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

<b>Header Text:</b> c4591001	
<b>Visit:</b> Unplanned - New Unscheduled Visit	<b>Form:</b> UNPLANNED VISIT
<b>Form Version:</b> 22-Apr-2020 21:04	<b>Form Status:</b> Not Started
<b>Site No:</b> 1003	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Subject No:</b> 10031113	<b>Subject Initials:</b> ---
<b>Generated By:</b> pfe.levissc	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04

<b>Unplanned Assessments</b>	
------------------------------	--

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	worsening of interstitial lung disease	Oct/17/2020 U NK:UNK	YES	<a href="#">Repeating Pages</a>
2. DELETED	ADVERSE EVENT	2	community acquired pneumonia	Oct/14/2020 U NK:UNK	YES	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	positive autoantibody status	Oct/20/2020 U NK:UNK	YES	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	respiratory failure	Jan/11/2021 U NK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[worsening of interstitial lung disease]
4.	Start Date Time:	Oct/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	4
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? NO  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? YES  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
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: [worsening of interstitial lung disease]

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

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?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020409757]

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[community-acquired pneumonia]
4.	Start Date Time:	Oct/14/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	4
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  <del>Is this serious event associated with congenital anomaly or birth defect?</del> NO  <del>Did this serious event result in death?</del> NO  <del>Did this serious event require or prolong hospitalization?</del> NO  <del>Did this serious event result in persistent or significant disability/incapacity?</del> NO  Is this serious event life threatening? YES  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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Deleted

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

9.	Is this event related to study treatment:	<del>NOT RELATED</del> If Not Related to study treatment(s), this event is due to: <del>OTHER</del> If Other, specify: [community acquired pneumonia]
10.	Latest Action Taken with Study Treatment:	<del>NOT APPLICABLE</del>
11.	Was a Concomitant Medication given?	<del>YES</del>
12.	Was a Non-Drug Treatment given?	<del>YES</del>
13.	What was the outcome of this adverse event?:	<del>RECOVERING/RESOLVING</del>
14.	Did the adverse event cause the subject to be discontinued from the study?	<del>NO</del>
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[positive autoantibody status]
4.	Start Date Time:	Oct/20/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [possible scleroderma]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[respiratory failure]
4.	Start Date Time:	Jan/11/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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: [interstitial lung disease]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021026385]

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

**Medication Error**

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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. DELETED				Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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

**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).	Not Applicable  [ ]	<a href="#">Comments</a>
5.	Date:	Not Applicable  //	<a href="#">Comments</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1. DELETED	1	CORTICOSTEROIDS	NO	Solu-MEDROL	60	<a href="#">Repeating Pages</a>
2. DELETED					250	<a href="#">Repeating Pages</a>
3. DELETED	3	CORTICOSTEROIDS	NO	prednisone	60	<a href="#">Repeating Pages</a>
4. DELETED	4	CORTICOSTEROIDS	NO	prednisone	50	<a href="#">Repeating Pages</a>

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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

**Concomitant Medications**

1.	What is the medication identifier?	[4]
2.	Category:	CORTICOSTEROIDS
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).	[Solu-MEDROL]
5.	Dose:	[60]
6.	Dose Unit:	mg
7.	Dose Frequency:	BID
8.	Route:	INTRAVENOUS
9.	Start Date:	Oct/22/2020
10.	Ongoing?	NO End Date: Oct/24/2020

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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

**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:	[250]
6.	Dose Unit:	mg
7.	Dose Frequency:	BID
8.	Route:	INTRAVENOUS
9.	Start Date:	Oct/24/2020
10.	Ongoing?	NO End Date: Oct/26/2020

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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

**Concomitant Medications**

1.	What is the medication identifier?	[3]
2.	Category:	CORTICOSTEROIDS
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).	[prednisone]
5.	Dose:	[60]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	Oct/27/2020
10.	Ongoing?	NO  End Date: Nov/2/2020

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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

**Concomitant Medications**

1.	What is the medication identifier?	[4]
2.	Category:	CORTICOSTEROIDS
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).	[prednisone]
5.	Dose:	[50]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	Oct/27/2020
10.	Ongoing?	YES

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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?	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisc

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

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.lewissc

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

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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	[ ]
----	-----------	-----

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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	Jan/13/2021
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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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 NOT willing to return for Vaccination 3 OR otherwise not eligible
----	---	--

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

**Treatment Unblinded**

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisc

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

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

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-02-2021 14:03:54 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	symptoms not new or worsening on 04Dec2020 however not fully resolved.



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Comments  
on Oct/15/2020

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
4	Dec-01-2020 08:37:17 (UTC-05:00) Eastern Time (US & Canada)	Lauren Mitchell (pfe.lschneggenburger)	Subjects admission was from 14OCT2020 - 16OCT2020
4	Nov-30-2020 12:11:16 (UTC-05:00) Eastern Time (US & Canada)	Lauren Mitchell (pfe.lschneggenburger)	Subjects first admission was from 14OCT2020 - 16OCT2020 Subjects second admission was from 17OCT2020 - 26OCT2020

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Oct/15/2020

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

**Form Status:** Incomplete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
Form	Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Oct/15/2020

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

**Form Status:** Incomplete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
1	Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Oct/15/2020

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

**Form Status:** Incomplete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
2	Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
2	Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Oct/15/2020

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

**Form Status:** Incomplete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
3	Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
3	Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Oct/15/2020

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

**Form Status:** Incomplete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
4	Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
4	Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Oct/15/2020

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

**Form Status:** Incomplete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
5	Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
5	Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Oct/15/2020

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

**Form Status:** Incomplete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
6	Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
6	Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Oct/15/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
3	Dec-01-2020 08:36:17 (UTC-05:00) Eastern Time (US & Canada)	Lauren Mitchell (pfe.lschneggenburger)	Unknown

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

Item	Date	User	Comment
4	Jan-20-2021 11:45:45 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

Item	Date	User	Comment
5	Jan-20-2021 11:46:49 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe mcriddle)	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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

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
Mary Criddle	N/A	Jan-26-2021 12:15:24 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Edward Walsh	Approved	Jan-21-2021 21:33:20 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, EdwardWalsh, 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.

Madison Murphy	N/A	Nov-18-2020 10:12:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
----------------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Edward Walsh	Approved	Nov-17-2020 07:21:59 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, EdwardWalsh, 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.

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Mary Criddle	N/A	Nov-16-2020 08:47:42 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
--------------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Edward Walsh	Approved	Nov-13-2020 13:25:39 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, EdwardWalsh, 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.

Mary Criddle	N/A	Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
--------------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Edward Walsh	Approved	Nov-02-2020 07:50:39 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, EdwardWalsh, 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.

Mary Criddle	N/A	Oct-27-2020 14:42:04 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
--------------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Edward Walsh	Approved	Oct-27-2020 11:10:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, EdwardWalsh, 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.

Mary Criddle	N/A	Oct-23-2020 14:33:32 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
--------------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Edward Walsh	Approved	Oct-23-2020 09:09:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, EdwardWalsh, 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.

Mary Criddle	N/A	Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
--------------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Edward Walsh	Approved	Oct-20-2020 19:49:42 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Affidavit:**

By my dated signature below, I, EdwardWalsh, 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.

Mary Criddle	N/A	Oct-15-2020 10:50:24 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
--------------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Edward Walsh	Approved	Sep-23-2020 16:43:22 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, EdwardWalsh, 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.

Mary Criddle	N/A	Sep-21-2020 09:06:00 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
--------------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Edward Walsh	Approved	Aug-26-2020 11:35:22 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Affidavit:**

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

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

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



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Jul-30-2020 13:38:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 13:38:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

*I. Consent Was:*

Date	Location	User	Value	Reason
Jul-30-2020 13:39:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jul/30/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031113

Generated By: pfe.lewissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Jul-30-2020 13:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10031113	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Jul-30-2020 13:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) /1946	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Jul-30-2020 13:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Jul-30-2020 13:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A ) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 13:39:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Jul-30-2020 15:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jul/30/2020	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:** 1003  
**Site Name:** (1003) Rochester Regional HealthRochester General Hospital  
**Subject No:** 10031113  
**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-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Inclusion Number:</b> : <b>Criterion Description:</b> Male or female participant 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) <b>Criterion Met?:</b> <b>Criterion ID:</b> (For Pfizer use only):	Initial Entry

*I.a Inclusion Number:*

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 1	Initial Entry

*I.a Criterion Description:*

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 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)	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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levissc

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

			mization (dependent upon study sta ge)	
--	--	--	---	--

**1.a Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> IN01A00	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Inclusi 2 on Nu mber:</b> <b>Criteria</b> Participants who are willi <b>on Des</b> ng and able to comply wit <b>criptio</b> h all scheduled visits, vacc <b>n:</b> ination plan, laboratory tes ts, lifestyle consideration s, and other study procedu res <b>Criteria</b> YES <b>on met</b> <b>?:</b> <b>Criteria</b> IN02A00 <b>on ID:</b> <b>(For P</b> <b>fizer u</b> <b>se only</b> <b>):</b>	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

**1.b Inclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 2	Initial Entry

**1.b Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 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-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> IN02A00	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Inclusion Number: 3	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<p><b>Criteria on Descriptio</b> Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study</p> <p><b>Criteria on met?:</b> YES</p> <p><b>Criteria on ID: (For Pfizer use only):</b> IN03A00</p>	
--	--	--	---	--

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

**I.c Inclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 3	Initial Entry

**I.c Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Healthy participants who are deter- mined 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-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> IN03A00	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Inclusi 4 on Nu mber:	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

			<p><b>Criteria Description:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol</p> <p><b>Criteria Met?:</b> YES</p> <p><b>Criteria ID:</b> IN04A00 (For Pfizer use only)</p>	
--	--	--	---	--

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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

**1.d Inclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 4	Initial Entry

**1.d Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 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-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> IN04A00	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Exclusion Number:	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			<p><b>Criteria Description:</b> 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><b>Criteria Met?:</b> NO</p> <p><b>Criteria ID:</b> EX01A00 (For Pfizer use only)</p>	
--	--	--	--	--

2.a Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 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-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX01A00	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion Description:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX02A00	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

**2.b Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 2	Initial Entry

**2.b Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 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-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX02A00	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Exclusion Number:	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

**Form Version:** 17-Jul-2020 21:53

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

			<p><b>Criteria Description:</b> 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><b>Criteria Met:</b> NO</p> <p><b>Criteria ID:</b> EX03A00 (For Pfizer use only)</p>	
--	--	--	--	--

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**2.c Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 3	Initial Entry

**2.c Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> History of severe adverse reaction a ssociated with a vaccine and/or seve ere allergic reaction (eg, anaphylaxi s) to any component of the study in tervention(s)	Initial Entry

**2.c Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX03A00	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Nu 4</b> <b>mber:</b> <b>Criterion De</b> Receipt of medicati <b>scription:</b> ons intended to pre vent COVID-19 <b>Criterion me</b> NO <b>t?:</b>	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:** 1003  
**Site Name:** (1003) Rochester Regional HealthRochester General Hospital  
**Subject No:** 10031113  
**Subject Initials:** ---  
**Generated By:** pfe.levisse  
**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Criterion ID:</b> EX04A00 (For Pfizer use only):	
--	--	--	--	--

**2.d Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 4	Initial Entry

**2.d Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Receipt of medications intended to prevent COVID-19	Initial Entry

**2.d Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX04A00	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Exclusion Number:	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<p><b>Criteria Description:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</p> <p><b>Criteria Met?:</b> NO</p> <p><b>Criteria ID: (For Pfizer use only):</b> EX08A00</p>	
--	--	--	---	--

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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

**2.e Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 8	Initial Entry

**2.e Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Immunocompromised individuals with known or suspected immunod efficiency, as determined by history and/or laboratory/physical examina tion	Initial Entry

**2.e Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX08A00	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Exclusi 10 on Nu mber:	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Bleeding diathesis or condition 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-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Exclusion Number: 11 <b>Criterion Description:</b> Women who are pregnant or breastfeeding <b>Criterion met?</b> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			<b>Criterion ID: ( EX11A00 For Pfizer use only):</b>	
--	--	--	--	--

**2.g Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 11	Initial Entry

**2.g Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Women who are pregnant or breastfeeding	Initial Entry

**2.g Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX11A00	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Number:</b> 12 <b>Criterion Description:</b> Previous vaccination with any coronavirus vaccine	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			<b>Criterion met NO</b> <b>?:</b> <b>Criterion ID: EX12A00</b> <b>(For Pfizer use only):</b>	
--	--	--	---	--

**2.h Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 12	Initial Entry

**2.h Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Previous vaccination with any coronavirus vaccine	Initial Entry

**2.h Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX12A00	Initial Entry

**2.i**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Number:</b> 13	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			<b>Criterion Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX13A01	
--	--	--	--	--

2.i Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX13A01	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

2.j

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Number:</b> 15 <b>Criterion Description:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study <b>Criterion met?:</b> NO <b>Criterion ID:</b> EX14A01 <b>(For Pfizer use only):</b>	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levissc

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

**2.j Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 15	Initial Entry

**2.j Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Receipt of blood/plasma products o r immunoglobulin, from 60 days be fore study intervention administrati on or planned receipt throughout th e study	Initial Entry

**2.j Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX14A01	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

2.k				
Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Number:</b> 16 <b>Criterion Description:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX15A01	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

2.k Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Participation in other studies invol ving study intervention within 28 d ays prior to study entry and/or duri ng study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> <b>Exclusio</b> 17 <b>n Numbe</b> <b>r:</b> <b>Criterion</b> Previous participation i <b>Descripti</b> n other studies involvin <b>on:</b> g study intervention co ntaining lipid nanoparti cles	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			<b>Criterion NO met?:</b> <b>Criterion EX16A01 ID: (For Pfizer use only):</b>	
--	--	--	--	--

**2.1 Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 17	Initial Entry

**2.1 Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

**2.1 Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**2.1 Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX16A01	Initial Entry

**2.m**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf	<b>Data Entry:</b> Exclus 22	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)		(pfe.ahelf)	<p><b>ion Nu mber:</b></p> <p><b>Criterion Description:</b> 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><b>Criterion ID:</b> NO</p> <p><b>Criterion ID:</b> EX21A01</p> <p><b>Criterion ID:</b> (For Pfizer use only):</p>	
--------------------	--	-------------	---	--

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

**2.m Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 22	Initial Entry

**2.m Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 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-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX21A01	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jul-30-2020 15:53:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jul/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jul-30-2020 15:53:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jul-30-2020 15:53:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Jul-30-2020 16:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Osteoarthritis <b>Start Date:</b> UNK/UNK/2000 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Jul-30-2020 16:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 16:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Osteoarthritis	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Jul-30-2020 16:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Jul-30-2020 16:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

*I.b*

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jul-30-2020 16:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> Anxiety <b>Start Date:</b> UNK/UNK/2000 <b>Ongoing:</b> YES	Initial Entry

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Jul-30-2020 16:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 16:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Anxiety	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Jul-30-2020 16:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Jul-30-2020 16:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Jul-30-2020 16:11:03 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 3	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Time (US & Canada)			:	
			<b>Medical History T</b>	Seasonal Allergies
			<b>Start Date:</b>	UNK/UNK/2017
			<b>Ongoing:</b>	YES

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Jul-30-2020 16:11:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 16:11:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Seasonal Allergies	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Jul-30-2020 16:11:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Jul-30-2020 16:11:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Oct-28-2020 11:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 4	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			<b>Medical History Term:</b> Interstitial Lung Disease <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> YES	
--	--	--	--	--

***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Oct-28-2020 11:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 11:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Interstitial Lung Disease	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Oct-28-2020 11:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Oct-28-2020 11:15:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031113

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Jul-30-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jul/30/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Jul-30-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 158.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Jul-30-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Jul-30-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 71.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Jul-30-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Jul-30-2020 16:03:04 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 22.0	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Jul-30-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.3 <b>Temperature Unit:</b> F <b>Temperature Locatio</b> <b>n::</b> FOREHEA D	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jul-30-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jul-30-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 97.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jul-30-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Jul-30-2020 16:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Jul-30-2020 16:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jul/30/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Jul-31-2020 10:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> 220530	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jul-30-2020 15:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jul-30-2020 15:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jul-30-2020 16:12:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-30-2020 15:57:29 (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-30-2020 15:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES Date of Collection:  Jul/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jul-30-2020 16:12:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> Sample ID: BGJWDX	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 16:12:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BGJWDX	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-30-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BGJWDY	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 16:12:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BGJWDY	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-30-2020 16:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BGJWDZ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jul-30-2020 16:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BGJWDZ	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-30-2020 16:13:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BKDYVG	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.d Sample ID**

Date	Location	User	Value	Reason
Jul-30-2020 16:13:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BKDYVG	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Jul-30-2020 16:13:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BKDYVH	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Jul-30-2020 16:13:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BKDYVH	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jul-30-2020 15:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jul-30-2020 15:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jul-30-2020 16:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-30-2020 15:57:22 (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-30-2020 15:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES Date of Collection:  Jul/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jul-30-2020 16:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> Sample ID: BGJWDB	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Jul-30-2020 16:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BGJWDB	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031113

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jul-30-2020 15:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jul-30-2020 15:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jul-30-2020 15:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jul-30-2020 15:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jul/30/2020 13:55	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jul-30-2020 15:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jul-30-2020 15:55:23 (UTC-05:00) Eastern	ACV0PFEINFP6000	Megan Helf	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

Time (US & Canada)		(pfe.ahelf)	
--------------------	--	-------------	--

**7. Route:**

Date	Location	User	Value	Reason
Jul-30-2020 15:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jul-30-2020 15:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 15:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisc

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Jul-30-2020 15:55:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS SU BJECT	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-20-2020 12:26:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> Aug/20/2020	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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.lewissc

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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> FA TI	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			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
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<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

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS  <b>Were fever or systemic sym ptoms present on the last d ay the Subject Diary was c ompleted?:</b> NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

2.e

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING <b>Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?:</b> NO	Initial Entry

*2.e Symptom:*

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

*2.f*

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A <b>Were fever or systemic sy mptoms present on the las t day the Subject Diary wa s completed?:</b> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED MUS CLE PAI N  <b>Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:</b>	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NEW OR WORSE NED MUSCL E 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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

**2.h**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or system NO ic symptoms present on the last day the Su bject Diary was comp leted?:</b>	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NEW OR WORSE NED JOI NT 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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactio ns present on the last day t he Subject Diary was com pleted?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG  <b>Were injection site reactio ns present on the last day the Subject Diary was co mpleted?:</b> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> Injection Site Reaction PAIN AT INJECTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 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-20-2020 12:27:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 30-Jul-2020 21:28

Site No: 1003

Subject No: 10031113

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.4 <b>Temperature Unit:</b> F <b>Temperature Location::</b> FOREHE AD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 97.4	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Aug-20-2020 12:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> FOREHEAD	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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-20-2020 12:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-20-2020 13:25:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-20-2020 12:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-20-2020 12:27:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> YES Date of Collection:  Aug/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-20-2020 13:25:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> Sample ID: BP57HR	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-20-2020 13:25:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BP57HR	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Aug-20-2020 15:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-20-2020 15:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-20-2020 15:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-20-2020 15:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> Aug/20/2020 13:04	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-20-2020 15:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-20-2020 15:21:52 (UTC-05:00) Eastern	ACV0PFEINFP6000	Emily Pierce	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

Time (US & Canada)

(pfe.epierce)

**7. Route:**

Date	Location	User	Value	Reason
Aug-20-2020 15:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-20-2020 15:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 15:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-21-2020 09:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**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 09:07:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  Were fever or systemic sy N mptoms present on the last O day the Subject Diary was completed?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom::</b> FA TI	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:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital  
**Subject No:** 10031113 **Subject Initials:** ---  
**Generated By:** pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

			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
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS <b>Were fever or systemic sy</b> NO <b>mptoms present on the las</b> <b>t day the Subject Diary wa</b> <b>s completed?:</b>	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:</b>	Initial Entry

*2.e Symptom:*

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

*2.f*

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW OR WORSE NED MU SCLE 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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

2.h

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED 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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW OR WORSE NED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-21-2020 09:07:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SW ELL ING  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-21-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-21-2020 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-21-2020 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-21-2020 12:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 09:07:19 (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 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES Date of Collection:  Sep/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-21-2020 12:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> Sample ID: BPYL6L	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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

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 12:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BPYL6L	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-21-2020 12:19:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BNWKBS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 12:19:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BNWKBS	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-21-2020 12:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BNWKBT	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 12:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BNWKBT	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-05-2021 01:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 1: Closed	Per site confirmation_PD tracker updated
Mar-04-2021 07:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	This is correct PD
Mar-04-2021 04:34:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	PDQ: Date of visit at V4_MONTH6_L is out of window for 1 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. "[rajkun SDQ=148077]"
Mar-02-2021 08:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Feb/26/2021	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

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
Mar-02-2021 08:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-02-2021 08:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-02-2021 08:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 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
Mar-02-2021 08:28:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> same as convalescent blood	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

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

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-22-2020 23:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 3: Closed	severe sepsis added
Oct-22-2020 13:23:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 3: Answered	AE completed in CRF
Oct-22-2020 07:28:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 3: Opened	SAE RECON:AER#2020409757 severe sepsis, possible pneumonia(onset date:14Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-15-2020 10:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-15-2020 10:50:22 (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.
Oct-15-2020 10:50:22 (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.

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/15/2020

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Oct-15-2020 10:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> Oct/15/2020	Initial Entry
---	-----------------	--------------------------------	-----------------------------------	---------------

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

Date	Location	User	Value	Reason
Oct-15-2020 10:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

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

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Oct/15/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-03-2021 03:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Malerato Mloi (pfe.moloim)	Query 1: Closed	Response satisfies query
Feb-02-2021 14:04:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-02-2021 14:04:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Dec/4/2020	Changed Information
Feb-02-2021 14:03:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Last Symptom Resolved date is a future date compared to when it was entered. Please correct.
Feb-02-2021 14:03:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-02-2021 14:03:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Dec/4/2021	Changed Information
Jan-19-2021 07:23:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nishanthi Audhimoalam (pfe.audhin)	Query 1: Opened	DM: Next visit should be entered only if all the symptoms at this visit resolved. If resolved, please review and update the date of last symptom resolved as appropriate. If not, please move details from next visit into this visit. Thank you.
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> YES	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry
---	-----------------	--------------------------------	---------------------------	---------------

4.b

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> YES	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			Symptom YES Present:	
--	--	--	----------------------	--

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

4.g

--

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED SORE THROAT <b>Symptom NO Present:</b>	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present NO</b> :	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/15/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**4.h Symptoms:**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms - Other:</b> weakness	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

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

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> weakness	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Oct/15/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-15-2020 10:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/15/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Oct-15-2020 10:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Oct-15-2020 10:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Oct-15-2020 10:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Oct-15-2020 10:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Oct-15-2020 10:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Oct-15-2020 10:55:30 (UTC-05:00) Eastern	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> CEPHEID XPERT XPRESS SA	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Oct/15/2020

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)			RS-COV-2 TEST	
--------------------	--	--	---------------	--

**7. Test Result:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-15-2020 10:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEGATIVE	Initial Entry



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/15/2020**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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**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
Oct-15-2020 10:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-15-2020 10:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-15-2020 10:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020 10:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: 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.
Oct-15-2020 10:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 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
Oct-15-2020 10:54:13	ACV0PFEINFP6000	Mary Criddle	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern  
Time (US & Canada)

(pfe.mcriddle) swab obtained on site

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/15/2020**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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-15-2020 10:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-15-2020 10:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-15-2020 11:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 10:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 10:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES Date of Collection:  Oct/15/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-15-2020 11:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> Sample ID: BPYL9X	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-15-2020 11:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BPYL9X	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/15/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Oct/15/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/15/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Type of Practitioner</b> URGENT : CARE <b>Occurrence of Visit</b> NO <b>s or Contacts:</b>	Initial Entry

*1.d Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> URGENT CARE	Initial Entry

*1.d Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

*1.e*

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Type of Practiti</b> TELEPHONE <b>oner:</b> CONSULTATI ON <b>Occurrence of</b> NO <b>Visits or Conta</b> <b>cts:</b>	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Oct/15/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**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
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 10:57:42	ACV0PFEINFP6000	Mary Criddle	<b>Data Entry:</b>	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/15/2020

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mcriddle)	YES Has the subject been in intensive care due to potential COVID-19 illness?  NO	
--	--	----------------	--	--

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail  
on Oct/15/2020

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

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-15-2020 10:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History  
on Oct/15/2020

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Oct-15-2020 10:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION STATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Oct-15-2020 10:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Oct-15-2020 10:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Dec-02-2020 06:02:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 2: Closed	Response satisfies query
Dec-01-2020 17:47:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Query 2: Answered	Changed data per query
Dec-01-2020 03:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teena Patra (pfe.patrat02)	Query 2: Opened	DM: Please confirm if Comment entered needs to be recorded in appropriate data point. Please confirm and correct else clarify, thank you.

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History  
on Oct/15/2020

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Nov-30-2020 15:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (pfe.shahr4)	Query 1: Closed	Response satisfies query
Nov-30-2020 12:10:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-30-2020 12:10:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NO Discharge Date:  Oct/16/2020	New Information
Nov-29-2020 09:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (pfe.shahr4)	Query 1: Opened	CLIQUERY: Please enter on the CRF form any available information ( pulse oxymet, respiratory treatment, and others). Please make every effort to obtain these information. Please confirm that the subject hospitalization status is still ongoing.
Oct-15-2020 10:58:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Oct/15/2020

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

**Form Status:** Incomplete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Initial Entry
Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Initial Entry
Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Initial Entry
Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Initial Entry
Mar-12-2021 07:24:13 (UTC-05:00) Eastern	ACV0PFEINFP6000	Megan Helf	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Oct/15/2020

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

**Form Status:** Incomplete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)		(pfe.ahelf)	
--------------------	--	-------------	--

**5. Start Date:**

Date	Location	User	Value	Reason
Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Initial Entry
Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Mar-12-2021 07:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Initial Entry
Mar-12-2021 07:24:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Oct/15/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-15-2020 11:01:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNES S	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Jan-25-2021 21:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-21-2021 11:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	will update diagnosis
Jan-21-2021 00:06:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical Thank you; however Resp Illness Diagnosis currently remains 'severe sepsis'
Jan-20-2021 12:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	change term to interstitial lung disease possible scleroderma
Jan-14-2021 18:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Event term is Severe Sepsis, the original SAE (#2020409757); however, final SAE terms were Interstitial Lung Disease and Possible Scleroderma. Please review diagnosis, and update as applicable.
Oct-15-2020 11:01:18	ACV0PFEINFP6000	Mary Criddle	<b>Data Entry:</b>	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Oct/15/2020

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe mcriddle)	YES <i>Respiratory Illness Diagnosis:</i>  severe sepsis  Date of Diagnosis:  Oct/14/2020	
--	--	----------------	--	--

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-15-2020 11:01:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 4	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY -  
Audit Trail

**Form Version:** 17-Jul-2020 21:53

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Created	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Rochester General Hospital Lab 1425 Portland Ave. Rochester N Y 14621	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-15-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 329 <b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> 14.1 <b>Not Done::</b>	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020**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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 10.0  <i>Unit</i> mg/L	
Oct-15-2020 11:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	New Information
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 329 <b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry
Oct-15-2020 11:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	New Information
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/15/2020**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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.a Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Oct-15-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 14.1	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Oct-15-2020 11:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b>	New Information
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Oct-15-2020 11:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 10.0  <i>Unit</i> mg/L	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defin</b> 30	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)			<b>ed Identifier:</b>	
			<b>Test::</b> Alanine Aminotransferase_PX30	
			<b>Result::</b> 24	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i> 10	
			<i>High</i> 49	
			<i>Unit</i> U/L	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History  
on Oct/15/2020**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Alanine Aminotransferase_PX30	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 24	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <i>Low</i> 10  <i>High</i> 49  <i>Unit</i> U/L	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defin</b> 28 <b>ed Identifier:</b> <b>Test::</b> Aspartate Aminotr ansferase_PX28	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Result::</b> 40	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			7	
			<i>High</i>	
			37	
			<i>Unit</i>	
			U/L	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Aspartate Aminotransferase_PX2 8	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 40	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b>  <i>Low</i> 7  <i>High</i> 37  <i>Unit</i> U/L	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 35 <b>d Identifier:</b> <b>Test::</b> Alkaline Phosph atase_PX35	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Result::</b> 96	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			46	
			<i>High</i>	
			116	
			<i>Unit</i>	
			U/L	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History  
on Oct/15/2020**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Alkaline Phosphatase_PX35	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 96	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Low 46  High 116  Unit U/L	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Bilirubin_P X21	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/15/2020

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Result::</b> .9	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			.3	
			<i>High</i>	
			1.2	
			<i>Unit</i>	
			mg/dL	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History  
on Oct/15/2020**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> .9	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b>  Low .3  High 1.2  Unit mg/dL	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 47 <b>d Identifier:</b> <b>Test::</b> Blood Urea Nitr ogen_PX47	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Result::</b> 16	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			8	
			<i>High</i>	
			20	
			<i>Unit</i>	
			mg/dL	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History  
on Oct/15/2020**Form Version:** 17-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Blood Urea Nitrogen_PX47	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 16	Initial Entry

**5.f LNMT**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b>  <i>Low</i> 8  <i>High</i> 20  <i>Unit</i> mg/dL	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 48 <b>entifier:</b> <b>Test::</b> Creatinine_P X48	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Result::</b> .9	
			<b>Not Done::</b>	
			<b>Lab Normal Range</b> <i>Low</i>	
			:	<i>.7</i>
				<i>High</i>
				1.2
				<i>Unit</i>
				mg/dL

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> .9	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-15-2020 11:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b>  <i>Low</i> .7  <i>High</i> 1.2  <i>Unit</i> mg/dL	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

**Form Version:** 17-Jul-2020 21:53

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Queries, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Rochester General Hospital 1425 Portland Ave Rochester NY 1462 1	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> 16.1 <b>Not Done::</b>	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Queries, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			<b>Lab Normal Range</b> <i>Low</i> : 13  <i>High</i> 18  <i>Unit</i> g/dL	
--	--	--	--	--

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 16.1	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <i>Low</i> 13  <i>High</i> 18  <i>Unit</i> g/dL	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.b**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 2 entifier:</b> <b>Test::</b> Hematocrit_ PX2 <b>Result::</b> 48 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 40  <i>High</i> 52  <i>Unit</i> %	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Queries, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 48	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Low 40  High 52  Unit %	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 3</b> <b>entifier:</b> <b>Test::</b> Erythrocytes_PX3	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Result::</b> 4.82	
			<b>Not Done::</b>	
			<b>Lab Normal Range</b> <i>Low</i>	
			:	4.40
				<i>High</i>
				6.20
			<i>Unit</i>	
			/uL	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 4.82	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Mar-13-2021 12:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Reissued:Opened	Thanks for the response, form has been unfreeze, please update as per below query
Mar-11-2021 21:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Reissued:Candidate	Clin: Please unfreeze for update
Mar-11-2021 08:19:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	please unfreeze for update
Mar-10-2021 17:11:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Opened	Clin: Please the Erythrocytes Unit should be "10^12/L" instead of "/uL". Please update accordingly

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <i>Low</i> 4.40  <i>High</i> 6.20  <i>Unit</i> /uL	Initial Entry
---	-----------------	--------------------------------	---	---------------

**5.d**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 5 <b>Test::</b> Platelets_P X5 <b>Result::</b> 179 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 150  <i>High</i> 450  <i>Unit</i> 10^3/uL	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Queries, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 179	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Low 150  High 450  Unit 10 <sup>3</sup> /uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 7</b> <b>entifier:</b> <b>Test::</b> Leukocytes_PX7	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Result::</b> 4.5	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			4.0	
			<i>High</i>	
			11.0	
			<i>Unit</i>	
			10 <sup>3</sup> /uL	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Queries, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 4.5	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Low 4.0  High 11.0  Unit 10 <sup>3</sup> /uL	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-16-2020 12:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608	Changed Information

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Result::</b> 85% <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 45 <i>High</i> 75 <i>Unit</i> %	
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 85 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 45 <i>High</i> 75 <i>Unit</i> %	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 608	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Neutrophils_PX608	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Oct-16-2020 17:37:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-16-2020 12:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-16-2020 12:41:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 85%	Changed Information
Oct-16-2020 06:56:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4988800;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Queries, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

				appropriate.
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 85	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <i>Low</i> 45  <i>High</i> 75  <i>Unit</i> %	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-16-2020 12:42:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0% <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0  <i>High</i> 5  <i>Unit</i> %	Transcription Error
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Test::</b> Eosinophils_ PX609	
			<b>Result::</b> 0	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i> 0	
			<i>High</i> 5	
			<i>Unit</i> %	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Oct-16-2020 17:37:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-16-2020 12:42:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-16-2020 12:42:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 0%	Transcription Error
Oct-16-2020 06:56:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4988798;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Queries, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

				appropriate.
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 0	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 5  <i>Unit</i> %	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-16-2020 12:42:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Monocytes_PX612 <b>Result::</b> 0% <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0  <i>High</i> 15  <i>Unit</i> %	Transcription Error

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

5.h				
Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 0 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0  <i>High</i> 15  <i>Unit</i> %	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 612	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Monocytes_PX612	Initial Entry

**5.h Result:**

Date	Location	User	Value	Reason
Oct-16-2020 17:37:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-16-2020 12:42:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-16-2020 12:42:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> i 0%	Transcription Error
Oct-16-2020 06:56:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4988799;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Queries, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

				appropriate.
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry</b> : 0	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 15  <i>Unit</i> %	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-16-2020 12:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_ PX610 <b>Result::</b> 0% <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0  <i>High</i> 3  <i>Unit</i> %	Transcription Error
Oct-15-2020 11:56:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined</b> 610	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)			<b>Identifier:</b>	
			<b>Test::</b>	Basophils_ PX610
			<b>Result::</b>	0
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b>	<i>Low</i> 0  <i>High</i> 3  <i>Unit</i> %

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 610	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Oct-16-2020 17:37:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-16-2020 12:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-16-2020 12:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 0%	Transcription Error
Oct-16-2020 06:56:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4988796;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Queries, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

				appropriate.
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry</b> : 0	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 3  <i>Unit</i> %	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> .2 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1.0  <i>High</i> 4.8  <i>Unit</i> 10^3/uL	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> Lymphocytes_PX611	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Oct-16-2020 17:37:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-16-2020 12:46:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	absolute value
Oct-16-2020 06:56:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4988797;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> . .2	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Oct/15/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Canada)				
---------	--	--	--	--

<i>5.j LNMT</i>				
Date	Location	User	Value	Reason
Oct-15-2020 11:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <i>Low</i> 1.0  <i>High</i> 4.8  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Oct/15/2020

**Form Version:** 17-Jul-2020 21:53

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-15-2020 11:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Oct/15/2020

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-15-2020 11:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-15-2020 12:40:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 80 <b>Diastolic::</b> 53 <b>Respiratory Rate in respir</b> <b>ations/minute:</b> 20 <b>Heart Rate in beats/minute</b> <b>:</b> 3	New Information
Oct-15-2020 12:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 8 0 <b>Diastolic::</b> 5 3 <b>Respiratory Rate in respira</b> <b>tions/minute:</b> 2 0 <b>Heart Rate in beats/minute</b> <b>:</b> 9 9	New Information
Oct-15-2020 11:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 8 0 <b>Diastolic::</b> 5 3 <b>Respiratory Rate in respira</b> <b>tions/minute:</b> 1 8 <b>Heart Rate in beats/minute</b> <b>:</b> 9 9	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Oct/15/2020

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-15-2020 11:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-19-2020 01:14:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Closed	Per site confirmation
Oct-16-2020 12:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Query 1: Answered	is clinically significant as it relates to his infection
Oct-16-2020 07:46:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe ks66)	Query 1: Reissued:Opened	DM: Kindly confirm Systolic BP 80 recorded is clinically significant or not, thank you.
Oct-15-2020 11:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Query 1: Answered	Original value is correct
Oct-15-2020 11:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 80 is outside of Normal Range 90 - 140.
Oct-15-2020 11:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 80	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Oct-17-2020 06:30:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sharat Nair (pfe nairs51)	Query 1: Closed	Response satisfies query
Oct-16-2020 12:52:56 (UTC-05:00) Eastern	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Query 1: Answered	is clinically significant as it

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Oct/15/2020

**Form Version:** 17-Jul-2020 21:53

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)				relates to his infection
Oct-16-2020 07:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe ks66)	Query 1: Reissued:Opened	DM: Kindly confirm Diastolic BP 53 recorded is clinically significant or not, thank you.
Oct-15-2020 11:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Query 1: Answered	Original value is correct
Oct-15-2020 11:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 53 is outside of Normal Range 60 - 90.
Oct-15-2020 11:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 53	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Oct-15-2020 12:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 20	New Information
Oct-15-2020 11:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 18	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Oct-15-2020 12:40:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 103	New Information
Oct-15-2020 11:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 99	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail  
on Oct/15/2020

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

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-15-2020 11:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/15/2020

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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Oct-15-2020 11:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-15-2020 11:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 98.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-15-2020 11:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Oct-15-2020 11:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 98.0	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Audit Trail  
on Oct/15/2020

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

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-30-2020 12:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Form Created	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: OXYGENATION PARAMETERS - eCRF Audit Trail History on Oct/15/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Nov-30-2020 12:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> Oct/15/2020 23:51	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Nov-30-2020 12:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> 98	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Dec-02-2020 01:32:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 1: Closed	Response is entered
Dec-01-2020 17:47:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Query 1: Answered	Original value is correct
Dec-01-2020 08:36:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> Unknown	Initial Entry
Dec-01-2020 01:27:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "FiO2 (Fraction of Inhaled Oxygen)" is missing. Kindly review and update.

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail  
on Oct/15/2020

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

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-15-2020 12:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History  
on Oct/15/2020

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-15-2020 12:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Oct-15-2020 12:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> CHEST	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Oct-15-2020 12:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> X-RAY	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Oct-15-2020 12:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> ABNORMAL <i>If abnormal, specify findings:</i>  increased retrocardiac airspace opacity of left lower zone, con- cerning for pneumonia.	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/13/2021

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

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-03-2021 00:59:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 4: Closed	Closed, Convalescent visit updated.
Mar-02-2021 08:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 4: Answered	happened on 26Feb
Feb-26-2021 07:35:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 4: Reissued:Opened	PDQ RQ2: As per query response CONVA visit is scheduled for 24Feb21 , however no conva visit is updated hence please check and update else clarify.
Feb-24-2021 02:04:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 4: Reissued:Candidate	PDQ RQ2: Thank you for the response, please update the details once available else clarify.
Feb-22-2021 11:05:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 4: Answered	subject has appointment for out of window convalescent visit on 24 Feb 2021
Feb-22-2021 06:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 4: Reissued:Opened	PDQ RQ1: Thank you for response, please confirm whether subject was contacted for CONVA visit and accordingly, enter CONVA visit details, else confirm planned CONVA

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - 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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

				visit date.
Feb-19-2021 10:12:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 4: Answered	subject no longer qualified for participation in the study due to contraindicated medication
Feb-18-2021 01:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 4: Opened	PDQ: Convalescent visit is missing and 35 days (36) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify.
Jan-22-2021 01:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 3: Closed	Response satisfies query
Jan-21-2021 11:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 3: Answered	Changed data per query
Jan-21-2021 05:28:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Bembem Takhellambam (pfe.takheb)	Query 3: Opened	DM: Date of Visit is completed but Self Swab CRF is not initiated. Please review and update the data as appropriate. Thanks
Jan-15-2021 13:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-15-2021 13:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/13/2021	Transcription Error

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - 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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-15-2021 13:33:36 (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-15-2021 13:33:36 (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-15-2021 13:33:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 13:33:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_B	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Jan/13/2021**Form Version:** 14-Jan-2021 02:23**Site No:** 1003**Subject No:** 10031113**Generated By:** pfe.levissc**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-15-2021 13:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b>	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - 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, Frozen**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**4.a Symptoms:**

Date	Location	User	Value	Reason
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> NO	Initial Entry
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b>	Initial Entry

**4.b Symptoms:**

Date	Location	User	Value	Reason
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - 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, Frozen

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

4.c

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> YES	Initial Entry
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b>	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry
Jan-15-2021 13:43:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - 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, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)			<b>Symptom Present:</b>	
--------------------	--	--	-------------------------	--

**4.d Symptoms:**

Date	Location	User	Value	Reason
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom</b> NO <b>Present:</b>	Initial Entry
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom</b> <b>Present:</b>	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - 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, Frozen

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Symptoms NEW LOSS OF TASTE OR SMELL Symptom Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - 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, Frozen

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

4.g

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Symptom NEW OR INCREASED SORE THROAT Symptom Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Symptoms: DIARRHEA Symptom Present NO	Initial Entry
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Symptoms: DIARRHEA	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - 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, Frozen

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			Symptom Present	
			:	

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> Symptoms: VOMITING Symptom Present: NO	Initial Entry
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> Symptoms: VOMITING Symptom Present:	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 13:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 13:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - 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, Frozen

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Jan-15-2021 13:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms - Other:</b>	Transcription Error <b>(DELETED)</b>
Jan-15-2021 13:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms - Other:</b>	Transcription Error
Jan-15-2021 13:43:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Symptoms - Other:</b> shortness of breath	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-15-2021 13:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b>	Transcription Error <b>(DELETED)</b>
Jan-15-2021 13:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b>	Transcription Error
Jan-15-2021 13:43:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> shortness of breath	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Jan/13/2021

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-15-2021 13:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcridde)	Form Deleted	Transcription Error
Jan-15-2021 13:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcridde)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Deleted, Frozen

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Jan-15-2021 13:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Jan-15-2021 13:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Jan-15-2021 13:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Jan-15-2021 13:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Jan-15-2021 13:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Jan/13/2021

**Form Version:** 06-Jul-2020 21:54

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Jan-15-2021 13:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> CEPHEID XPRT XPRESS SA RS-COV-2 TEST	Initial Entry
---	-----------------	--------------------------------	---	---------------

**7. Test Result:**

Date	Location	User	Value	Reason
Jan-15-2021 13:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - 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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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-21-2021 11:16:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-21-2021 11:16:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-21-2021 11:16:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 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-21-2021 11:16:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> swab pfe	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - 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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-15-2021 13:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-15-2021 13:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 14:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Close per site query response
Jan-19-2021 08:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	This is correct - subject hospitalized and swab was taken from hospital sample on date of admittance.
Jan-15-2021 16:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-15-2021 14:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection 11/Jan/2021 is different from Date of Visit 13/Jan/2021. Please review and update as appropriate, else clarify.
Jan-15-2021 14:28:18	ACV0PFEINFP6000	Mary Criddle	<b>Data Entry:</b>	Transcription Error

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - 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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)		(pfe mcriddle)	YES Date of Collection:  Jan/11/2021	
Jan-15-2021 13:58:47 (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.
Jan-15-2021 13:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection 15/Jan/2021 is different from Date of Visit 13/Jan/2021. Please review and update as appropriate, else clarify.
Jan-15-2021 13:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> YES Date of Collection:  Jan/15/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-15-2021 16:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BPYLJP	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-15-2021 16:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BPYLJP	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - 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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

*1.a*

Date	Location	User	Value	Reason
Jan-15-2021 13:52:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b>	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Jan-15-2021 13:52:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

*1.b*

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 2 - 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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			<b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i>  1	
--	--	--	---	--

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 2 - 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:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Type of Practitioner</b> URGENT : CARE <b>Occurrence of Visit</b> NO <b>s or Contacts:</b>	Initial Entry

***I.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***I.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

***I.e***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55	ACV0PFEINFP6000	Mary Criddle	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - 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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.mcriddle)	<b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	
--	--	----------------	--	--

***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> OTHER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - 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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-15-2021 13:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES Has the subject been in intensive care due to potential COVID-19 illness?  NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail  
on Jan/13/2021

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

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-15-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History  
on Jan/13/2021

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Jan-15-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	<b>Data Entry:</b> HOSPITALIZATION STATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Jan-15-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Jan-15-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/11/2021	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Jan-15-2021 13:52:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO Discharge Date:  Jan/13/2021	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/18/2020

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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
Nov-18-2020 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> Nov/18/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-18-2020 10:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> COVID_A1	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/18/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**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
Nov-18-2020 10:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-18-2020 10:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-18-2020 10:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-18-2020 10:12:23 (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.
Nov-18-2020 10:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> YES Date of Collection:  Nov/18/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-18-2020 10:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> Sample ID: BPYLC7	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/18/2020

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

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-18-2020 10:15:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BPYLC7	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-18-2020 10:15:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BNWKMP	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-18-2020 10:15:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BNWKMP	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-18-2020 10:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BNWKKP	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-18-2020 10:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BNWKKP	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Feb/26/2021

**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:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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
Mar-02-2021 08:27:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Feb/26/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-02-2021 08:27:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> COVID_B1	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Feb/26/2021

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Mar-02-2021 08:27:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-02-2021 08:27:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-02-2021 09:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Mar-02-2021 08:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-02-2021 08:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES Date of Collection:  Feb/26/2021	Changed Information
Mar-02-2021 08:27:44 (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-02-2021 08:27:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Assessment is a future date relative to when it was entered. Please

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Feb/26/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

				correct.
Mar-02-2021 08:27:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES Date of Collection:  Mar/26/2021	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-02-2021 09:15:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> low draw	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-02-2021 09:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID: BPYLTD</b>	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-02-2021 09:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BPYLTD	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Mar-02-2021 09:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID: BVR36N</b>	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Mar-02-2021 09:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BVR36N	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

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

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Sep-21-2020 09:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-21-2020 09:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-21-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

**Form Status:**

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

**Form Status:**

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-04-2020 15:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridde)	Form Deleted	New Information
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridde)	Form Created	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

**Form Status:**

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Form Created	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

**Form Status:**

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcridle)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Nov-05-2020 17:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 5: Closed	Response satisfies query
Nov-04-2020 08:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 5: Answered	term should be worsening of interstitial lung disease
Nov-04-2020 06:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Closed	Term in Safety database updated to 'worsening of interstitial lung disease'
Nov-03-2020 08:10:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Reissued:Opened	SAE RECON 2: Per PSSR, no follow up form was received on Oct 28.Event term is still reported as ILD (interstitial lung disease of possibly due to scleroderma). Please confirm if scleroderma is a valid SAE and should be added in AE CRF.
Nov-02-2020 16:42:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 5: Reissued:Opened	The event term has been reported to safety as "possible scleroderma". If

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

				considered appropriate, please update AE log as well.
Nov-02-2020 15:09:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 5: Answered	diagnosis of scleroderma has not been confirmed.
Oct-30-2020 10:32:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 5: Opened	CLINICAL_ The event "possible scleroderma" was reported as serious in Safety database but missing in this AE log. Per CRF completion guidelines section 8.50. "record all observed or volunteered AE." Please update accordingly. Thank you.
Oct-30-2020 06:30:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitior)	Query 4: Reissued:Candida te	SAE recon: pending confirmation from PSSR if a follow up AEM form was received
Oct-29-2020 14:00:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Oct-29-2020 08:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 4: Answered	term updated in safety data base on 28 Oct 2020
Oct-29-2020 08:15:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 3: Answered	leukocytosis with bandemia results are part of same illness of worsening Interstitial Lung Disease. additional SAE not needed.
Oct-29-2020 05:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitior)	Query 4: Reissued:Opened	SAE RECON 1:Term in AE CRF was updated to 'worsening of interstitial lung disease'. Please confirm if a follow up AEM form to update term in Safety database
Oct-28-2020 23:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	Clinical With removal of Sepsis event term, please review the leukocytosis

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

				with bandemia as noted in the SAE report, for reporting as an independent laboratory adverse event
Oct-28-2020 10:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Oct-28-2020 10:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> worsening of interstitial lung disease	New Information
Oct-28-2020 09:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Opened	SAE RECON:AER#2020409757 possible scleroderma(onset date:14Oct2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-27-2020 15:36:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query
Oct-27-2020 14:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 3: Answered	Interstitial lung disease replaces both sepsis, possible pneumonia.
Oct-27-2020 09:13:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 2: Answered	Follow up AEM form was submitted to update the term in Safety database on 23 Oct 2020
Oct-26-2020 22:31:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Reissued:Opened	SAE RECON 1:Please confirm if a follow up AEM FORM was submitted to update the term in Safety database.
Oct-26-2020 15:04:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL Please clarify if new term Interstitial lung Dz replaces old term Possible pneumonia only, or also replaces old term Sepsis with left shift/ IV

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

				antibiotic treatment. If only 1 term replaced; please add the other on AE CRF.
Oct-26-2020 15:00:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-26-2020 14:43:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 2: Answered	interstitial lung disease is replacing previously reported diagnosis of severe sepsis and possible pneumonia
Oct-24-2020 09:14:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON: AER#2020409757, the term was updated to 'interstitial lung disease' while retained as 'severe sepsis and possible pneumonia' in Safety database. Please confirm correct term. If safety update is required, submit a follow-up SAE Form.
Oct-23-2020 14:33:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-23-2020 14:33:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> interstitial lung disease	New Information
Oct-23-2020 09:58:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - Per SAE report, subject has a second event of diffuse pneumonia vs pulmonary edema. Please enter event, recognizing term is not yet known and may need to be modified with further data
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> severe sepsis	Initial Entry

**4. Start Date Time:**

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date	Location	User	Value	Reason
Nov-10-2020 02:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Nov-09-2020 13:52:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-09-2020 13:52:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Oct/17/2020 UNK:UNK	New Information
Nov-09-2020 05:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020409757,onset date was updated to 17Oct2020 in SDB however, recorded as 14Oct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Oct/14/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Oct-22-2020 23:16:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE severe sepsis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birt h defect?  NO  Did this serious event result in death?  NO  Did this serious event require or prolong hospitalization?  NO  Did this serious event result in persistent or significant disabilit y/incapacity?  NO  Is this serious event life threate ning?  YES	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			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.**

Date	Location	User	Value	Reason
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 09:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  worsening of interstitial lung disease	New Information
Oct-27-2020 15:37:44 (UTC-05:00)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Eastern Time (US & Canada)				
Oct-27-2020 14:42:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: A nswered	Transcription Error
Oct-27-2020 14:42:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcridle)	<b>Data Entr y:</b> NOT REL ATED If Not Re lated to st udy treat ment(s), t his event is due to:  OTHE R  <i>If Oth er, spe cify:</i>  inter stitia l lun g dis ease	Transcription Error
Oct-26-2020 14:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: C losed	Query closed; will follow for SAE update including the reported influenza test results
Oct-26-2020 14:52:54 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 2: O pened	Please review "If not related to study treatment other" field,

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

Canada)				the following text was indicated in the comment field [sepsis]. Any symptoms, AEs or other key data should be collected on the Adverse event page. Please review and update as necessary. "[survea03 SDQ=21043]"
Oct-23-2020 13:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	subject was tested for flu A and B and was negative. Safety report updated.
Oct-23-2020 09:55:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Please clarify in a SAE Safety update if during hospitalization subject has been tested for influenza (YES/NO), with results if Yes
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)





Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 01:49:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Per clinical confirmation outcome updated to recovering/resolving in Argus
Nov-03-2020 07:20:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:C andidate	SAE RECON: Pending SDB update
Nov-02-2020 11:01:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	follow up AEM will be completed today to reflect that subject is recovering/resolving

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

Oct-30-2020 06:18:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotior)	Query 1: Reissued:O pened	SAE RECON 2:Thank you for the update. However, outcome in safety database is still unknown. Please confirm if a follow up AEM form was submitted to update outcome in Safety database.
Oct-29-2020 08:08:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-29-2020 08:08:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> RECOVERING/RE SOLVING	New Information
Oct-29-2020 05:10:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotior)	Query 1: Reissued:O pened	SAE RECON 1:Per query response 'subject is still recovering/resolving', however the outcome in AE CRF was recorded as NOT RECOVERED/RESOLVED and UNKNOWN in Safety database. Please confirm correct outcome and update both databases.
Oct-28-2020 10:59:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Query 1: Answered	subject is still recovering/resolving
Oct-28-2020 08:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotior)	Query 1: Opened	SAE RECON:AER#2020409757,outcome was reported as UNKNOWN to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> NOT RECOVERED /NOT RESOLVED	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

& Canada)				
-----------	--	--	--	--

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

Date	Location	User	Value	Reason
Oct-22-2020 12:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Oct-22-2020 23:16:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020409757	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> community acquired pneumonia	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> Oct/14/2020 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 4	Initial Entry
---	-----------------	--------------------------------	-------------------------	---------------

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Nov-04-2020 15:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE community acquired pneumonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birt h defect?  NO  Did this serious event result in death?  NO  Did this serious event require o r prolong hospitalization?  NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031113

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

			<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>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
--	--	--	---	--

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

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

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<p><b>Data Entry:</b> NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:</p> <p>OTHER</p> <p><i>If Other, specify:</i></p> <p>community acquired pneumonia</p>	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55	ACV0PFEINFP6000	Mary Criddle	<b>Data Entry:</b>	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete, Deleted

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

(UTC-05:00) Eastern Time (US & Canada)		(pfe mcriddle)	NOT APPLICABLE	
--	--	----------------	----------------	--

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 08:48:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Mar-12-2021 12:13:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Mar-10-2021 07:59:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 4: Answered	05Mar2021 I faxed updated SAE report (2020409757) indicating autoantibody was a non-serious event.
Mar-09-2021 01:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued:Opened	Clinical - Thank you, however 05Mar21 SAE report still lists autoantibody as one of the SAE Events. To have this event 'non-serious' in both AE and SAE, remove autoantibody from SAE event section of SAE
Mar-05-2021 16:07:15 (UTC-05:00) Eastern	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 4: Answered	SAE report 2020409757 will be

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)				faxed today reflecting non-serious event
Mar-05-2021 14:48:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued:Opened	Clinical - thank you; please submit the Change to "non-Serious" for this event - where it is still recorded as serious - to the SAE report (#2020409757) ASAP
Mar-03-2021 16:02:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 4: Answered	inform changed
Mar-03-2021 10:19:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued:Opened	CLINICAL - to clarify, is the Event 'positive autoantibody status' an AE or a serious AE? If non-serious, change here on AE log CRF, and send SAE update to change event from serious to non-serious
Mar-03-2021 10:18:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Closed	Response satisfies query
Mar-03-2021 09:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 5: Answered	SAE sent with updated term positive autoantibody status
Mar-02-2021 14:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 5: Reissued:Opened	SAE RECON1: Term should match in both CRF and Safety databases. Term was reported as 'possible scleroderma' in Safety database thus if correct in inform, please submit and follow up SAE form. If correct in Safety database, update CRF.

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

Mar-02-2021 08:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Query 4: Answered	See other query, needs clarification.
Mar-02-2021 08:02:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Query 5: Answered	Please clarify. Original AE was reported as possible scleroderma, as patient was to have further work up based on positive auto antibody status. Term was changed per query and now should be changed again? Unsure what is needed?
Mar-02-2021 04:55:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 5: Opened	SAE RECON: AER#2020409757,the term was reported as 'possible scleroderma' in Safety database while updated to 'positive autoantibody status' in AE CRF. Please confirm correct term.If safety update is required, please submit a follow-up form.
Feb-28-2021 22:17:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Reissued:Opened	Clinical - Please review serious event status and update as appropriate, with change in event term. Please update the event term and also serious status (if required) in a SAE report (#2020409757) update
Feb-26-2021 08:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	I updated AE to just reflect positive autoantibody status.

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031113

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Feb-26-2021 08:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> positive autoantibody status	I updated AE to just reflect positive autoantibody status.
Feb-25-2021 23:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical - If possible scleroderma is not a defined event, please review this event term for clarification/update. SAE reports positive autoantibody status (SCL-70) in association with event 'possible scleroderma'
Feb-25-2021 15:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Closing query on a deleted AE
Feb-25-2021 15:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Closing query on a deleted AE
Feb-18-2021 15:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Feb-18-2021 15:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-18-2021 15:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> possible scleroderma with posi tive autoantibody status	New Information
Feb-16-2021 17:04:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical - If possible scleroderma is not a defined event, please review this event term for clarification/update. SAE reports positive autoantibody status (SCL-70) in association with event 'possible scleroderma'

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1003**Subject No:** 10031113**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-16-2021 17:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	CLINICAL - If possible scleroderma is NOT an event, please remove as a serious EVENT from SAE for ILD (#2020409757). SAE narrative has 'started on steroids for a dx of ILD (ILD of possibly due to scleroderma)'; update as required.
Jan-26-2021 12:09:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 2: Answered	no
Jan-25-2021 21:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Possible Scleroderma SAE; however SAE (#2021026385; Resp failure) states 'possibility of scleroderma considered although thought unlikely as other tests such as ANA & ANCA serologies were negative.' Is Scleroderma and event if subject has ILD.
Nov-06-2020 07:06:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotr)	Query 1: Closed	updated query text
Nov-06-2020 07:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotr)	Query 1: Opened	SAE RECON: possible scleroderma(Onset date:14Oct2020) is not reported to Safety database but marked serious on AE CRF. However, missing in Safety database. Please confirm if the SAE form was

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

				submitted
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> possible scleroderma	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> Oct/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 3	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
Mar-08-2021 19:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Mar-03-2021 16:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE positive autoantibody status: Response to "Is the adverse event serious?" is 'No' but

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1003**Subject No:** 10031113**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

				"Serious Adverse Event Number" is present.
Mar-03-2021 16:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	it is PART of a serious adverse event it is NOT an SAE by itself
Nov-09-2020 05:03:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	event recorded in SDB
Nov-06-2020 07:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Nov-06-2020 07:07:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Opened	SAE RECON: possible scleroderma(Onset date:20Oct2020) is not reported to Safety database but marked serious on AE CRF. However, missing in Safety database. Please confirm if the SAE form was submitted
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE possible scleroderma: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in	Initial Entry

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1003  
**Subject No:** 10031113  
**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete  
**Site Name:** (1003) Rochester Regional HealthRochester General Hospital  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:04

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

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

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			possible scleroderma	
--	--	--	----------------------	--

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-04-2020 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-08-2021 19:15:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b>	downgraded to non serious

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

*15. Serious Adverse Event Number: For Pfizer Use Only*

Date	Location	User	Value	Reason
Nov-09-2020 05:02:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020409757	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031113

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> respiratory failure	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/11/2021 UNK:UNK	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-20-2021 09:18:10 (UTC-05:00) Eastern	ACV0PFEINFP6000	Kathryn Sewell	Query 1: Closed	Response satisfies query

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)		(pfe.sewelk02)		
Jan-15-2021 12:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-15-2021 12:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 2	Transcription Error
Jan-14-2021 18:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Severity grade is 3; however, SAE criteria include Life-Threatening which per protocol Sect 10.3.3 is defined as Grade 4. Please harmonize reporting, and update where applicable
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 3	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-16-2021 17:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Jan-26-2021 12:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 4: Answered	sending SAE update today
Jan-25-2021 21:45:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical Followup on 11Jan2021 Covid test (negative); the most recent SAE update (21Jan21) did not include this

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1003**Subject No:** 10031113**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

				relevant laboratory test. Please submit a SAE (#2021026385) update with this lab.
Jan-20-2021 23:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Query closed; will follow for SAE update with the requested COVID test info
Jan-20-2021 11:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 3: Answered	COVID test during hospitalization on 11 Jan 2021 was negative. will update in safety report.
Jan-20-2021 09:18:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Jan-20-2021 09:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021026385] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-18-2021 05:00:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-15-2021 14:04:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Jan-15-2021 14:04:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Jan-15-2021 14:04:08 (UTC-05:00) Eastern	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	New Information

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

Time (US & Canada)			<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> <p>NO</p>	
Jan-14-2021 23:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021026385] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-14-2021 18:39:47	ACV0PFEINFP6000	Kathryn	Query 2: Opened	CLINICAL Serious

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

(UTC-05:00) Eastern Time (US & Canada)		Sewell (pfe.sewelk02)		criteria are Hosp and Life-threatening; however, SAE report serious criterion is Hosp. Please review, harmonize reporting, and update where applicable.
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE respiratory failure: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<p><b>Data Entry:</b></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> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important seri</p>	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

			ous 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.

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  interstitial lung disease	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry
---	-----------------	--------------------------------	--------------------------	---------------

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

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Jan-18-2021 05:00:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2021026385	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-26-2021 12:15:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Deleted	Transcription Error
Jan-13-2021 15:17:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Created	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

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, Deleted, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-20-2021 11:44:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-13-2021 15:17:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Jan-20-2021 11:44:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-13-2021 15:17:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Jan-20-2021 11:44:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-13-2021 15:17:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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
------	----------	------	-------	--------

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

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, Deleted, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Jan-26-2021 15:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 2: Closed	Response satisfies query
Jan-26-2021 12:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 2: Answered	will delete
Jan-23-2021 20:50:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 2: Opened	Please delete this record when there is no data to be reported. Thank you.
Jan-21-2021 19:41:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Closed	Response satisfies query
Jan-20-2021 11:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-20-2021 11:44:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-20-2021 11:44:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b>	Transcription Error
Jan-20-2021 01:11:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Minal Pathak (pfe.patham13)	Query 1: Opened	ClinQuery: ConMed: Please note the following conmed is not a vaccination and is not required to be listed: dapsone 100 mg PO QD
Jan-19-2021 20:00:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Candidate	ClinQuery: ConMed: Please note the following conmed is not a vaccination and is not required to be listed: dapsone 100

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**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, Deleted, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

				mg PO QD
Jan-13-2021 15:17:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> dapsone 100 mg PO QD	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Jan-20-2021 11:46:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-20-2021 11:46:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b>	Transcription Error
Jan-13-2021 15:17:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Nov/17/2020	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.lewissc

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

**Form Status:**

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-09-2020 13:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Deleted	does not meet guidelines
Nov-04-2020 15:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Form Created	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

**Form Status:**

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-09-2020 13:47:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcridle)	Form Deleted	does not meet guidelines
Nov-04-2020 15:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcridle)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

**Form Status:**

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 09:15:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridde)	Form Deleted	Changed Information
Nov-04-2020 16:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridde)	Form Created	

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

**Form Status:**

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 08:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridde)	Form Deleted	Changed Information
Nov-04-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridde)	Form Created	



Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-04-2020 15:56:31 (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
Nov-04-2020 15:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> CORTICOSTEROIDS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-04-2020 15:56:31 (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
Nov-09-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Closed	Response satisfies query
Nov-09-2020 13:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	does not meet guidelines
Nov-09-2020 06:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	ClinQuery: Please note this medication does not meet the dose/duration criteria listed in

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Deleted, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

				section 6.5.1 to be listed on this log. please remove as appropriate. thanks
Nov-09-2020 05:12:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Candidate	ClinQuery: Please note this medication does not meet the dose/duration criteria listed in section 6.5.1 to be listed on this log. please remove as appropriate. thanks
Nov-04-2020 15:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Solu-MEDROL	Initial Entry

**5. Dose:**

Date	Location	User	Value	Reason
Nov-04-2020 15:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 60	Initial Entry

**6. Dose Unit:**

Date	Location	User	Value	Reason
Nov-04-2020 15:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> mg	Initial Entry

**7. Dose Frequency:**

Date	Location	User	Value	Reason
Nov-04-2020 15:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> BID	Initial Entry

**8. Route:**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

Nov-04-2020 15:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> INTRAVENOUS	Initial Entry
---	-----------------	--------------------------------	-----------------------------------	---------------

**9. Start Date:**

Date	Location	User	Value	Reason
Nov-04-2020 15:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> Oct/22/2020	Initial Entry

**10. Ongoing?**

Date	Location	User	Value	Reason
Nov-04-2020 15:56:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> NO End Date: Oct/24/2020	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levissc

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-09-2020 13:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Changed Information
Nov-04-2020 15:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-09-2020 13:46:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u>	Changed Information
Nov-04-2020 15:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> CORTICOSTEROIDS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-09-2020 13:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Changed Information
Nov-04-2020 15:58:28 (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
------	----------	------	-------	--------

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Incomplete, Data Complete, Deleted, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

Nov-09-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Closed	Response satisfies query
Nov-09-2020 13:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-09-2020 13:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b>	Changed Information
Nov-09-2020 06:06:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Opened	ClinQuery: Please note this medication does not meet the dose/duration criteria listed in section 6.5.1 to be listed on this log. please remove as appropriate. thanks
Nov-09-2020 05:12:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Candidate	ClinQuery: Please note this medication does not meet the dose/duration criteria listed in section 6.5.1 to be listed on this log. please remove as appropriate. thanks
Nov-04-2020 15:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> solu-MEDROL	Initial Entry

**5. Dose:**

Date	Location	User	Value	Reason
Nov-04-2020 15:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 250	Initial Entry

**6. Dose Unit:**

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Date	Location	User	Value	Reason
Nov-04-2020 15:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Nov-04-2020 15:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> BID	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Nov-04-2020 15:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Nov-04-2020 15:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> Oct/24/2020	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Nov-04-2020 15:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> NO End Date:  Oct/26/2020	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-04-2020 16:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-04-2020 16:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> CORTICOSTEROIDS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-04-2020 16:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Nov-16-2020 11:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe hassaa38)	Query 1: Closed	Response satisfies query
Nov-16-2020 09:15:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-15-2020 09:29:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe frantu)	Query 1: Opened	Clin: Please note corticosteroids are only collected to visit 3 for p2/3

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Deleted, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031113**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

				subjects. Subject has completed V3 in sep. please delete. See CRF Completion GLs 4.11.1 - Thank You!
Nov-15-2020 07:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe hassaa38)	Query 1: Candidate	Clin: Please note corticosteroids are only collected to visit 3 for p2/3 subjects. Subject has completed V3 in sep. please delete. thanks
Nov-04-2020 16:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> prednisone	Initial Entry

**5. Dose:**

Date	Location	User	Value	Reason
Nov-04-2020 16:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 60	Initial Entry

**6. Dose Unit:**

Date	Location	User	Value	Reason
Nov-04-2020 16:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> mg	Initial Entry

**7. Dose Frequency:**

Date	Location	User	Value	Reason
Nov-04-2020 16:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> QD	Initial Entry

**8. Route:**



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Date	Location	User	Value	Reason
Nov-04-2020 16:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<b>Data Entry:</b> ORAL	Initial Entry

**9. Start Date:**

Date	Location	User	Value	Reason
Nov-04-2020 16:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<b>Data Entry:</b> Oct/27/2020	Initial Entry

**10. Ongoing?**

Date	Location	User	Value	Reason
Nov-04-2020 16:00:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<b>Data Entry:</b> NO End Date:  Nov/2/2020	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.lewissc

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-04-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 4	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-04-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> CORTICOSTEROIDS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-04-2020 16:02:18 (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
Nov-16-2020 11:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe hassaa38)	Query 1: Closed	Response satisfies query
Nov-16-2020 08:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-15-2020 07:37:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe hassaa38)	Query 1: Opened	Clin: Please note corticosteroids are only collected to visit 3 for p2/3

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031113

Subject Initials: ---

Generated By: pfe.levisse

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

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

				subjects. Subject has completed V3 in sep. please delete. thanks
Nov-04-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> prednisone	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Nov-04-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> 50	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Nov-04-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Nov-04-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Nov-04-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Nov-04-2020 16:02:18	ACV0PFEINFP6000	Mary Criddle	<b>Data Entry:</b>	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

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

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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

(UTC-05:00) Eastern Time (US & Canada)

(pfe mcriddle)

Oct/27/2020

**10. Ongoing?**

Date	Location	User	Value	Reason
Nov-04-2020 16:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> YES	Initial Entry

**Header Text:** c4591001

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

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031113

**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
Mar-12-2021 07:26:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Mar-12-2021 07:26:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Mar-02-2021 12:09:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe francm73)	Query 1: Closed	Response satisfies query
Mar-02-2021 08:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	entered - happened on 26Feb
Mar-02-2021 01:16:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kirubakaran Kesavan Kendhapedi (pfe kendak01)	Query 1: Opened	DM: Visit 4 is overdue based on expected visit window. Please enter data or, if visit will never occur, mark Date of Visit as 'Not Done' with form level comment. If subject is no longer in the trial, complete the Disposition FUP form.
Sep-21-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Jul-30-2020 16:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Jul-30-2020 15:53:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Sep-21-2020 09:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levisse

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

**Form Status:** Data Complete, Verified

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

Sep-21-2020 09:07:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jul/30/2020	Initial Entry
Jul-30-2020 16:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jul/30/2020	Initial Entry
Jul-30-2020 15:53:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jul/30/2020	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031113

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

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

[Back to Form](#)

*1. Casebook Signature*

Date	Location	User	Value	Reason
Aug-26-2020 11:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Edward Walsh (pfe.ewalsh)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae3d6a\Final\Final On: 01-Apr-2021 04:33 (GMT)