

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** COHORT\_SELECTION

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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	06 OCT 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/19/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 15-Sep-2020 21:54

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10051293]
2.	Birth Date:	(b) (6)/1960
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

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

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Oct/19/2020
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:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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/2017
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HIGH CHOLESTEROL]
	Start Date:	Jan/UNK/2020
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[VASECTOMY]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2005

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CERVICAL FUSION]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RIGHT INGUINAL HERNIA REPAIR]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Alcohol Use Disorder]
	Start Date:	UNK/UNK/1973
	Ongoing:	YES

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** HIV STATUS

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/19/2020
2.	Weight:	[206.6]
3.	Unit:	LB
4.	Height:	[72.3]
5.	Unit:	in
6.	Body Mass Index:	[27.8]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[96.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** RANDOMIZATION

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Oct/19/2020
2.	Randomization Number:	[270739]
3.	Randomization Group:	[ ]

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1005  
**Subject No:** 10051293  
**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1005) Rochester Clinical Research, Inc.  
**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: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BJ3W8K]
5.b	Sample ID	[BJ3W8L]
5.c	Sample ID	[BPB06J]
5.d	Sample ID	[BPB06K]
5.e	Sample ID	[BPB06L]

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPB0J6]
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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:	Oct/19/2020 08:47
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Not Done _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Done _____	<a href="#">Comments</a>



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 20-Feb-2021 02:16

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

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

**Vital Signs**

1.	Date:	Not Done _____ //	<a href="#">Comments</a>
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**Vital Signs Details**

2.a	Record Identifier:	Not Done _____ 1	
	Temperature:	Not Done _____ [ ]	<a href="#">Comments</a>
	Unit:	Not Done _____	<a href="#">Comments</a>
	Temperature Location:	Not Done _____	<a href="#">Comments</a>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

1.	Data Origin	Not Done _____	<a href="#">Comments</a>
2.	Sample Type	Not Done _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Done _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Done _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ [ ]
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VACCINATION

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

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

**Vaccination**

1.	Was there a temporary delay of vaccination?	Not Done _____	<a href="#">Comments</a>
2.	Treatment Name	Not Done _____ [ ]	<a href="#">Comments</a>
3.	Formulation:	Not Done _____	<a href="#">Comments</a>
4.	Dose Date Time:	Not Done _____ //	<a href="#">Comments</a>
5.	Anatomical Location:	Not Done _____	<a href="#">Comments</a>
6.	Body Side:	Not Done _____	<a href="#">Comments</a>
7.	Route:	Not Done _____	<a href="#">Comments</a>
8.	Actual Dose:	Not Done _____ [ ]	<a href="#">Comments</a>
9.	Unit:	Not Done _____	<a href="#">Comments</a>
10.	Timeframe Subject Was Observed	Not Done _____	<a href="#">Comments</a>
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done _____	<a href="#">Comments</a>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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	Nov/9/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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:	Nov/9/2020	
2.	Date of First Symptom Started:	Not Applicable _____ //	<a href="#">Comments</a>
3.	Symptoms Ongoing?	Not Applicable _____	<a href="#">Comments</a>

**Symptoms**

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

**Symptoms - Other**

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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.	Nov/8/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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:	Nov/8/2020
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:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[NALT UNKNOWN]



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[UNABLE TO CONTACT SUBJECT AT THIS TIME TO OBTAIN SWAB]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020      **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[NOT ABLE TO COLLECT UNABLE TO CONTACT SUBJECT AT TIME]

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION  
Nov/09/2020

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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:	NO
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:	YES Number of Visits or Contacts: [1]

**Health Care Utilization Other**

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

**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? YES
----	--	---

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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	ICU	Nov/8/2020	YES	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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:	ICU
3.	Admission Date:	Nov/8/2020
4.	Ongoing?	YES

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	1	YES	MECHANICAL VENTILATION	MECHANICAL VENTILATION	Nov/8/2020	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Respiratory Treatment**

1.	What is the treatment Identifier?	[1]
2.	Concomitant Non-drug Treatment Pre-specified:	YES
3.	Treatment:	MECHANICAL VENTILATION
4.	Treatment:	[MECHANICAL VENTILATION]
5.	Start Date:	Nov/8/2020
6.	Ongoing?	YES

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [ACUTE RESPIRATORY FAILURE]  Date of Diagnosis: Nov/8/2020
3.	Toxicity Grade:	4



**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE  
Nov/09/2020

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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: 10-Oct-2020 15:58

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.	CLINICAL CHEMISTR Y	Strong Memorial Labs 601 Elm wood Avenue Rochester, NY 14 642	Nov/10/ 2020	BLOO D	<b>Sponsor-Defi ned Identifie r</b>	<b>Test:</b>	<b>Res ult:</b>	<a href="#">Repeating Pages</a>
					329	C Reactive Prote in_PX329	[ ]	
					30	Alanine Aminotr ansferase_PX30	64	
					28	Aspartate Amino transferase_PX2 8	24	
					35	Alkaline Phosph atase_PX35	61	
					21	Bilirubin_PX21	0.5	
					47	Blood Urea Nitr ogen_PX47	12	
					48	Creatinine_PX4 8	0.79	

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Nov/09/2020

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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	[Strong Memorial Labs 601 Elmwood Avenue Rochester, NY 14642]
3.	Collection Date:	Nov/10/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[64]
	Not Done:	
	LNMT	Low [0] High [50] Unit U/L

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[24]
	Not Done:	
	LNMT	Low [0] High [50] Unit U/L
5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[61]
	Not Done:	
	LNMT	Low [40] High [130] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.5]
	Not Done:	
	LNMT	Low [0.0] High [1.2] Unit mg/dL

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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:	[12]
	Not Done:	
	LNMT	Low [6] High [20] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.79]
	Not Done:	
	LNMT	Low [0.67] High [1.17] Unit mg/dL

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
1.	HEMATOLOGY	Strong Memorial Labs 601 Elmwood Avenue Rochester, NY 14642	Nov/10/2020	BLOOD	1	Hemoglobin_PX1	13.7	<a href="#">Repeating Pages</a>
					2	Hematocrit_PX2	41	
					3	Erythrocytes_PX3	4.6	
					5	Platelets_PX5	234	
					7	Leukocytes_PX7	5.9	
					608	Neutrophils_PX608	4.0	
					609	Eosinophils_PX609	0.2	
					612	Monocytes_PX612	0.4	
					610	Basophils_PX610	0.1	
					611	Lymphocytes_PX611	1.3	
					2.	HEMATOLOGY	Strong Memorial Labs 601 Elmwood Avenue Rochester, NY 14642	
2	Hematocrit_PX2	[ ]						
3	Erythrocytes_PX3	[ ]						
5	Platelets_PX5	303						
7	Leukocytes_PX7	11.2						
608	Neutrophils_PX608	[ ]						

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
					609	Eosinophils_PX609	[ ]	
					612	Monocytes_PX612	[ ]	
					610	Basophils_PX610	[ ]	
					611	Lymphocytes_PX611	[ ]	

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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	[Strong Memorial Labs 601 Elmwood Avenue Rochester, NY 14642]
3.	Collection Date:	Nov/10/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[13.7]
	Not Done:	
	LNMT	Low [13.7] High [17.5] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[41]
	Not Done:	
	LNMT	Low [40] High [51] Unit %

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.6]
	Not Done:	
	LNMT	Low [4.6] High [6.1] Unit 10^3/uL
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[234]
	Not Done:	
	LNMT	Low [150] High [330] Unit 10^3/uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[5.9]
	Not Done:	
	LNMT	Low [4.2] High [9.1] Unit 10^3/uL

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[4.0]
	Not Done:	
	LNMT	Low [1.8] High [5.4] Unit 10^3/uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.2]
	Not Done:	
	LNMT	Low [0.0] High [0.5] Unit 10^3/uL
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.4]
	Not Done:	
	LNMT	Low [0.3] High [0.8] Unit 10^3/uL

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.1]
	Not Done:	
	LNMT	Low [0.0] High [0.1] Unit 10^3/uL
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[1.3]
	Not Done:	
	LNMT	Low [1.3] High [3.6] Unit 10^3/uL

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.leviscc

**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	[Strong Memorial Labs 601 Elmwood Avenue Rochester, NY 14642]
3.	Collection Date:	Nov/8/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[15]
	Not Done:	
	LNMT	Low [13.7] High [17.5] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[303]
	Not Done:	
	LNMT	Low [150] High [330] Unit 10^3/uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[11.2]
	Not Done:	
	LNMT	Low [4.2] High [9.1] Unit 10^3/uL

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit



**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date:	Vital Signs Details			Form Instance
1.	Nov/8/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	139	88	
2. DELETED	Not Applicable	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	Not Applicable	Not Applicable	

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID  
Nov/09/2020

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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:	Nov/8/2020
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[139]
	Diastolic:	[88]
	Respiratory Rate in respirations/minute:	[14]
	Heart Rate in beats/minute:	[114]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID  
Nov/09/2020

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Deleted

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

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

**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
----	-------	-------------------------------	--------------------------

**Vital Signs Details**

2-a	Record Identifier:	±	
	Systolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Diastolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Respiratory Rate in respirations/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Heart Rate in beats/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date:	Vital Signs Details		Form Instance
1.	Nov/8/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	95.0	
2. DELETED	Nov/8/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	100.0	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
Nov/09/2020

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Data Complete, Frozen

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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:	Nov/8/2020
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[95.0]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
Nov/09/2020

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Data Complete, Deleted

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.leviscc

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

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

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

**Vital Signs**

1.	Date:	Nov/8/2020
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[100.0]

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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.	Nov/8/2020 UNK:UNK	80	Unknown	<a href="#">Repeating Pages</a>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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:	Nov/8/2020 UNK:UNK	
2.	Arterial Blood Gases PaO2 (mmHg):	[80]	
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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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?	

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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.	Nov/8/2020	HEAD	CT SCAN	NORMAL	<a href="#">Repeating Pages</a>
2.	Nov/8/2020	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i>  Bilateral perihilar airspace & interstitial opacities -possible pulmonary edema vs. infection	<a href="#">Repeating Pages</a>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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:	Nov/8/2020
2.	Location of Assessment:	HEAD
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	NORMAL

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

**Imaging**

1.	Date of Assessment:	Nov/8/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Bilateral perihilar airspace & interstitial opacities -possible pulmonary edema vs. infection]

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit      **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit      **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** 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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

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	CARDIAC ARREST	Nov/8/2020 00:43	NO End Date Time:  Nov/8/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Acute Respiratory Failure	Nov/8/2020 00:43	YES	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Overdose	Nov/8/2020 00:43	NO End Date Time:  Nov/8/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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)	[CARDIAC ARREST]
4.	Start Date Time:	Nov/8/2020 00:43
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/8/2020 UNK:UNK
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? YES  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: [possible intentional overdose, or. poor choice of alcohol and drug abuse.]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020443745]

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute Respiratory Failure]
4.	Start Date Time:	Nov/8/2020 00:43
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? YES  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: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

11.	Was a Concomitant Medication given?	NO
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	[2020443745]

<b>Header Text:</b> c4591001		<b>Form:</b> ADVERSE EVENT REPORT
<b>Visit:</b> Logs - Unscheduled		<b>Form Status:</b> Data Complete, Frozen, Not Complete
<b>Form Version:</b> 22-Apr-2020 21:02		<b>Site Name:</b> (1005) Rochester Clinical Research, Inc.
<b>Site No:</b> 1005		<b>Subject Initials:</b> ---
<b>Subject No:</b> 10051293		<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levisse		
<a href="#">Back to Form</a> <a href="#">eCRF Audit Trail History</a> <a href="#">Form Audit Trail</a>		
<b>Adverse Event Report</b>		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Overdose]
4.	Start Date Time:	Nov/8/2020 00:43
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/8/2020 UNK:UNK
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? YES  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: [multi-drug ingestion]

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020443745]



**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.leviscc

**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>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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	[ ]

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

**Concomitant Medications**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

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

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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>

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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 - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vaccination**

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

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** DATE OF VISIT

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

**Site No:** 1005 **Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293 **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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisc

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

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Dec/14/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	LOST TO FOLLOW-UP
4.	Specify Status:	[SUBJECT IS LOST TO FOLLOW UP]

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Not Applicable _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Applicable _____	<a href="#">Comments</a>

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

			<a href="#">Comments</a>
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Not Applicable	



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	Dec/14/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	LOST TO FOLLOW-UP
4.	Specify Status:	[LOST TO FOLLOW UP]

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Not Applicable _____ //	<a href="#">Comments</a>
2.	Primary Reason for Unblinding:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Withdrawal Of Consent**

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

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/14/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** CASEBOOK SIGNATURE FORM

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

**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, Signed, Verified

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Matthew Davis	Approved	Mar-12-2021 13:19:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-19-2020 10:58:37 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-10-2021 15:24:58 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-10-2021 15:24:58 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Mar-10-2021 15:24:58 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 20-Feb-2021 02:16

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** VITAL SIGNS - TEMP - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-10-2021 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 20-Feb-2021 02:16

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-10-2021 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 20-Feb-2021 02:16

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Mar-10-2021 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 20-Feb-2021 02:16

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Mar-10-2021 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 20-Feb-2021 02:16

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Mar-10-2021 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-10-2021 15:25:30 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-10-2021 15:25:30 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Mar-10-2021 15:25:30 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Mar-10-2021 15:25:30 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Mar-10-2021 15:25:30 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

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**Form:** VACCINATION - Comments

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**Site Name:** (1005) Rochester Clinical Research, Inc.

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

[Back to Form](#)

Item	Date	User	Comment
3	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

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**Site No:** 1005

**Subject No:** 10051293

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**Site Name:** (1005) Rochester Clinical Research, Inc.

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

[Back to Form](#)

Item	Date	User	Comment
4	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

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**Site No:** 1005

**Subject No:** 10051293

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**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

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**Site No:** 1005

**Subject No:** 10051293

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**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

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

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**Subject No:** 10051293

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**Form:** VACCINATION - Comments

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**Subject Initials:** ---

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[Back to Form](#)

Item	Date	User	Comment
7	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

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

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**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VACCINATION - Comments

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
8	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

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**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

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**Subject Initials:** ---

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[Back to Form](#)

Item	Date	User	Comment
9	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

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**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
10	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done



**Header Text:** c4591001

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**Subject No:** 10051293

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**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
11	Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Done

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Dec-05-2020 08:02:32 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable
2	Nov-30-2020 13:16:37 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	
2	Nov-24-2020 15:12:26 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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[Back to Form](#)

Item	Date	User	Comment
3	Dec-05-2020 08:03:12 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable
3	Nov-30-2020 13:16:58 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	
3	Nov-24-2020 15:12:37 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4.a	Jan-06-2021 14:40:46 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	
4.a	Nov-24-2020 15:13:42 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable
4.a	Nov-16-2020 15:16:48 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Unknown

**Header Text:** c4591001

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4.b	Jan-06-2021 14:41:46 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	
4.b	Nov-24-2020 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable
4.b	Nov-16-2020 15:16:56 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Unknown

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**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4.c	Jan-06-2021 14:42:03 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	
4.c	Nov-24-2020 15:14:14 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable
4.c	Nov-16-2020 15:17:07 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Unknown

**Header Text:** c4591001

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

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

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**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4.d	Jan-06-2021 14:42:17 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	
4.d	Nov-24-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable
4.d	Nov-16-2020 15:17:15 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Unknown

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4.e	Jan-06-2021 14:42:30 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	
4.e	Nov-24-2020 15:14:43 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable
4.e	Nov-16-2020 15:17:24 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Unknown



**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4.f	Jan-06-2021 14:42:44 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	
4.f	Nov-24-2020 15:15:00 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable
4.f	Nov-16-2020 15:17:34 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Unknown

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4.g	Jan-06-2021 14:43:10 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	
4.g	Nov-24-2020 15:15:19 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable
4.g	Nov-16-2020 15:17:43 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Unknown

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4.h	Jan-06-2021 14:43:26 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	
4.h	Nov-24-2020 15:15:33 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable
4.h	Nov-16-2020 15:17:52 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Unknown

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4.i	Jan-06-2021 14:43:47 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	
4.i	Nov-24-2020 15:15:49 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable
4.i	Nov-16-2020 15:18:01 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Unknown

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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
Form	Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 10-Oct-2020 15:59

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen

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[Back to Form](#)

Item	Date	User	Comment
2.a	Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 10-Oct-2020 15:59

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**Site Name:** (1005) Rochester Clinical Research, Inc.

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 10-Oct-2020 15:59

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**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	Julie Mooney (pfe.jmooney)	Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
3	Nov-16-2020 15:32:08 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Unknown

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - Comments

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

**Form Status:** Data Complete, Verified

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-12-2021 11:21:40 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Applicable

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-12-2021 11:21:40 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Applicable

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact

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

**Site No:** 1005

**Subject No:** 10051293

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**Subject Initials:** ---

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[Back to Form](#)

Item	Date	User	Comment
2	Mar-12-2021 11:21:40 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Applicable

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - Comments

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete

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**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-12-2021 11:21:55 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Applicable

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** FURTHER VACCINATION CONFIRMATION - Comments

**Form Status:** Data Complete

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-12-2021 11:21:55 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Applicable



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** TREATMENT UNBLINDED - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-12-2021 11:21:13 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** TREATMENT UNBLINDED - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-12-2021 11:21:13 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

**Form:** TREATMENT UNBLINDED - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Mar-12-2021 11:21:13 (UTC-05:00) Eastern Time (US & Canada)	Jessica Fisher (pfe.jfisher)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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

Name	Signature Meaning	Date	Type	Action
Matthew Davis	Approved	Mar-12-2021 13:19:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, MatthewDavis, 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.

Julie Mooney	N/A	Feb-16-2021 12:43:41 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Davis	Approved	Jan-25-2021 08:48:16 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, MatthewDavis, 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.

Julie Mooney	N/A	Jan-22-2021 12:55:12 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Davis	Approved	Jan-20-2021 09:31:40 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Affidavit:**

By my dated signature below, I, MatthewDavis, 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.

Julie Mooney	N/A	Jan-06-2021 14:40:46 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Davis	Approved	Jan-05-2021 12:50:31 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, MatthewDavis, 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.

Chelsey LoMonaco	N/A	Dec-28-2020 14:15:23 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Davis	Approved	Dec-09-2020 08:25:48 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, MatthewDavis, 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.

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

Julie Mooney	N/A	Dec-05-2020 08:02:18 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
<b>Affidavit:</b> N/A				
Matthew Davis	Approved	Dec-02-2020 08:47:46 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
<b>Affidavit:</b> By my dated signature below, I, MatthewDavis, 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.				
Chelsey LoMonaco	N/A	Nov-30-2020 13:16:37 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
<b>Affidavit:</b> N/A				
Matthew Davis	Approved	Nov-25-2020 09:03:13 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
<b>Affidavit:</b> By my dated signature below, I, MatthewDavis, 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.				
Julie Mooney	N/A	Nov-23-2020 13:36:24 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
<b>Affidavit:</b> N/A				
Matthew Davis	Approved	Nov-17-2020 17:44:49 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

**Affidavit:**

By my dated signature below, I, MatthewDavis, 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.

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-19-2020 10:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 10:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

*I. Consent Was:*

Date	Location	User	Value	Reason
Oct-19-2020 10:50:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Oct/19/2020	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1005

Subject No: 10051293

Generated By: pfe.lewissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Oct-19-2020 10:50:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 10051293	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-19-2020 10:50:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6)/1960	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-19-2020 10:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Oct-19-2020 10:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 10:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-19-2020 10:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Oct-19-2020 10:58:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-19-2020 10:58:52 (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
Oct-19-2020 10:58:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051293

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

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

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Oct-19-2020 10:59:09 (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> OSTEOARTHRI TIS <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-19-2020 10:59:09 (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
Oct-19-2020 10:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> OSTEOARTHRTIS	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Oct-19-2020 10:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Oct-19-2020 10:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Oct-19-2020 10:59:35 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 2	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)			ber: Medical Histor y Term: Gastroesophageal ref lux disease Start Date: UNK/UNK/2018 Ongoing: YES	
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**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Oct-19-2020 10:59:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

**I.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Oct-19-2020 10:59:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Gastroesophageal reflux disease	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Oct-19-2020 10:59:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> UNK/UNK/2018	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Oct-19-2020 10:59:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> YES	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Oct-19-2020 10:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Numbe 3 r: Medical History HIGH CHOLEST Term: EROL Start Date: Jan/UNK/2020 Ongoing: YES	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.lewissc

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

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Oct-19-2020 10:59:52 (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
Oct-19-2020 10:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> HIGH CHOLESTEROL	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Oct-19-2020 10:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/UNK/2020	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Oct-19-2020 10:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Oct-19-2020 11:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 4 Medical History Te VASECTOMY rm: Start Date: UNK/UNK/2005 Ongoing: NO End Date:  UNK/UNK/2 005	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.lewissc

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

**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Oct-19-2020 11:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Oct-19-2020 11:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> VASECTOMY	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Oct-19-2020 11:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Oct-19-2020 11:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2005	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Oct-19-2020 11:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 5 : <b>Medical History Term:</b> CERVICAL FUSION <b>Start Date:</b> UNK/UNK/2013 <b>Ongoing:</b> NO End Date:  UNK/UNK/2013	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.lewissc

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

*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Oct-19-2020 11:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 11:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> CERVICAL FUSION	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Oct-19-2020 11:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Oct-19-2020 11:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2013	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Oct-19-2020 11:01:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 6 <b>mber:</b> <b>Medical Hist</b> RIGHT INGUINAL H <b>ory Term:</b> ERNIA REPAIR <b>Start Date:</b> UNK/UNK/2016 <b>Ongoing:</b> NO End Date:  UNK/UNK/2016	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.lewissc

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

***I.f Line/MH Number:***

Date	Location	User	Value	Reason
Oct-19-2020 11:01:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

***I.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Oct-19-2020 11:01:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RIGHT INGUINAL HERNIA REP AIR	Initial Entry

***I.f Start Date:***

Date	Location	User	Value	Reason
Oct-19-2020 11:01:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

***I.f Ongoing:***

Date	Location	User	Value	Reason
Oct-19-2020 11:01:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2016	Initial Entry

***I.g***

Date	Location	User	Value	Reason
Dec-07-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 7 : <b>Medical History Term:</b> Alcohol Use Disorder <b>Start Date:</b> UNK/UNK/1973 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

***I.g Line/MH Number:***

Date	Location	User	Value	Reason
Dec-07-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

***I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Dec-07-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Alcohol Use Disorder	Initial Entry

***I.g Start Date:***

Date	Location	User	Value	Reason
Dec-07-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> UNK/UNK/1973	Initial Entry

***I.g Ongoing:***

Date	Location	User	Value	Reason
Dec-07-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

*1. Select appropriate response - What is the subject HIV status?*

Date	Location	User	Value	Reason
Oct-19-2020 11:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> The subject is NOT known to be HI V POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1005

Subject No: 10051293

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 206.6	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 72.3	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 27.8	Initial Entry

**7.a**

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1005

Subject No: 10051293

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

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

Date	Location	User	Value	Reason
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 96.7 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-19-2020 11:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 1: Closed	Response satisfies query
Oct-19-2020 11:03:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	NCS PER PI
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.7 F is outside of Normal Range 97 - 99.5 F.
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 96.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-19-2020 11:02:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-19-2020 11:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-19-2020 11:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 270739	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

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
Oct-19-2020 12:03:16 (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-19-2020 12:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-19-2020 12:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 12:03:16 (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-19-2020 12:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Date of Collection:  Oct/19/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-19-2020 12:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BJ3W8K	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (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: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-19-2020 12:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BJ3W8K	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-19-2020 12:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BJ3W8L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 12:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BJ3W8L	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 12:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BPB06J	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 12:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BPB06J	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-20-2020 10:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BPB06K	Transcription Error
Oct-19-2020 12:03:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BPB06L	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-20-2020 15:34:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-20-2020 10:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-20-2020 10:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry</b> : BPB06K	Transcription Error
Oct-19-2020 16:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW5068779;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-19-2020 12:03:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry</b> : BPB06L	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Oct-19-2020 12:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BPB06L	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.e Sample ID**

Date	Location	User	Value	Reason
Oct-20-2020 15:34:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-20-2020 10:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	Original value is correct
Oct-19-2020 16:19:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW5068780;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-19-2020 12:03:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry</b> : BPB06L	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (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: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

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
Oct-19-2020 12:04:14 (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-19-2020 12:04:14 (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-19-2020 12:04:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Date of Collection:  Oct/19/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-19-2020 12:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BPB0J6	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-19-2020 12:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BPB0J6	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051293

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

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
Oct-19-2020 11:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-19-2020 11:02:49 (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
Oct-19-2020 11:02:49 (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
Oct-19-2020 11:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Oct/19/2020 08:47	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-19-2020 11:02:49 (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
Oct-19-2020 11:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Oct-19-2020 11:02:49 (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
Oct-19-2020 11:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 11:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**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
Oct-19-2020 11:03:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-10-2021 15:24:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Mar-10-2021 15:24:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Temperature:</b> Not Done <b>Temperature Unit:</b> Not Done <b>Temperature Location::</b> Not Done	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (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, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

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
Mar-10-2021 15:25:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	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-10-2021 15:25:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051293

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

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
Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Mar-12-2021 13:12:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh-Khiabani (pfe.youseb01)	Query 1: Closed	Response satisfies query
Mar-12-2021 11:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Query 1: Answered	Patient was lost to follow up on 14Dec2021 after hospitalization. Treatment eCRF should not have to be completed.
Mar-10-2021 23:50:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7668935;Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.lewissc

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

				appropriate.
Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry</b> : Not D one	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry
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*11. Was the subject observed for at least the protocol specified observation period after investigational product administration?*

Date	Location	User	Value	Reason
Mar-10-2021 15:25:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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
Jan-06-2021 14:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Jan-05-2021 07:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Date of Visit is after the Date of Completion/Discontinuation /Death on the Follow-Up Disposition form. Please review and update as appropriate.
Nov-17-2020 10:05:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 1: Closed	Response satisfies query
Nov-17-2020 08:43:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	Nasal Swab Self not obtained at this time
Nov-17-2020 02:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Opened	PDQ : Details of Sample ID and collection date for either Nasal Swab Self or Nasal Swab expected to be completed. Please check and update else clarify.
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-16-2020 15:15:10 (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.
Nov-16-2020 15:15:10 (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.

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Nov-16-2020 15:15:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/9/2020	Initial Entry
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**3. COVID-19 Illness Visit:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-16-2020 15:15:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-07-2021 02:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Closed	clinical query already for clarifying shortness of breath
Jan-06-2021 14:44:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	Original value is correct
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/9/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Jan-08-2021 12:14:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikh06)	Query 2: Closed	Response satisfies query
Jan-06-2021 14:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	PER CRA ANSWER EACH PRE-DEFINED SYMPTOMS SHOULD BE NO
Dec-08-2020 14:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikh06)	Query 2: Reissued:Opened	CLINQUERY: Please follow up with CRA. Inquire/Obtain information regarding ANY subject symptoms during episode of ACUTE RESPIRATORY FAILURE (e.g. Shortness of breath, etc.) and update CRF.



**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History  
**Form Version:** 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Not Complete  
**Site No:** 1005 **Site Name:** (1005) Rochester Clinical Research, Inc.  
**Subject No:** 10051293 **Subject Initials:** ---  
**Generated By:** pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

Dec-05-2020 08:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-05-2020 08:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-05-2020 08:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Transcription Error
Dec-03-2020 08:51:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikh06)	Query 2: Reissued:Opened	CLINQUERY: Symptoms Start date of 08NOV2020 is provided. What symptom was this? Please inquire with subject or from source regarding ANY subject symptoms during episode of ACUTE RESPIRATORY FAILURE (e.g. Shortness of breath, etc.) and update CRF.
Dec-01-2020 07:17:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	Symptoms reported were unknown - covid illness visit completed off of medical records per sponsor request
Nov-30-2020 16:20:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikh06)	Query 2: Opened	CLINQUERY: Per CCG 8.30, enter all symptoms that occur during the course of the illness (even if they are not present during the illness visit). Please enter/update this CRF to reflect all the symptoms that the participant reported throughout the illness
Nov-30-2020 13:17:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1005**Subject No:** 10051293**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Nov-30-2020 13:16:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b>	Initial Entry
Nov-25-2020 01:52:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Closed	Response satisfies query
Nov-25-2020 01:43:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Reissued:Opened	DM1: Please verify patient details and update when subject is having first sign and symptoms of Covid ILL due to which assessment has been done. Thank you.
Nov-24-2020 15:12:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-24-2020 06:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	unknown
Nov-24-2020 06:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	unknown
Nov-24-2020 06:43:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Divya M (pfe.md09)	Query 1: Opened	DM: Since all the symptoms are marked as Unknown, please review and clarify the date of first symptom reported. Please update data as appropriate.
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Dec-05-2020 08:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-05-2020 08:03:02 (UTC-05:00) Eastern	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Transcription Error

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020  
**Form Version:** 10-Oct-2020 16:02  
**Site No:** 1005  
**Subject No:** 10051293  
**Generated By:** pfe.levisse

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen, Not Complete  
**Site Name:** (1005) Rochester Clinical Research, Inc.  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:04

Time (US & Canada)				
Nov-30-2020 15:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 2: Closed	Response satisfies query
Nov-30-2020 13:17:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Nov-30-2020 13:17:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry
Nov-30-2020 13:16:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b>	Initial Entry
Nov-26-2020 07:28:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 2: Reissued:Opened	DM: Please review and update Symptoms Ongoing at item #3 with the help of CRA. Thank you.
Nov-25-2020 16:13:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	No is not an option only Not Done, N/A, or Unknown
Nov-25-2020 01:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Closed	Response satisfies query
Nov-25-2020 01:53:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 2: Opened	DM: Please update Symptom Present = NO instead not applicable for all symptoms field on this form. Thank you.
Nov-24-2020 15:13:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	Changed data per query
Nov-24-2020 15:12:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-24-2020 07:48:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 1: Reissued:Opened	Form should be completed for subjects who experience

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020  
**Form Version:** 10-Oct-2020 16:02  
**Site No:** 1005  
**Subject No:** 10051293  
**Generated By:** pfe.levisse

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen, Not Complete  
**Site Name:** (1005) Rochester Clinical Research, Inc.  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:04

				symptoms. If no symptoms experienced, then Date of Assessment should be entered, Date of First Symptom Started = Not Applicable, Symptom Ongoing? = Not Applicable & Symptom Present = NO for all symptoms
Nov-23-2020 13:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	unknown
Nov-23-2020 13:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	unknown
Nov-22-2020 23:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Reissued:Opened	DM : Symptoms ongoing is recorded as YES. However, Symptom present are recorded as unknown. Please review and update. Else, clarify.
Nov-19-2020 08:17:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	COVID illness visit completed off of hospital medical records - no symptoms listed on medical records - covid visit completed per sponsor request
Nov-18-2020 00:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 1: Reissued:Opened	DM: Per CRF completion guidelines section 8.30.5., If the symptoms were present AT ANY TIME during the Potential COVID-19 Illness, please enter/update this CRF to reflect all the symptoms that the

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1005**Subject No:** 10051293**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

				participant reported throughout the illness.
Nov-17-2020 08:40:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	correct as is
Nov-17-2020 07:29:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nishanthi Audhimoalam (pfe.audhin)	Query 1: Opened	DM Query: Symptoms present are Unknown. Please review and update the data as appropriate. Thank you.
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Jan-06-2021 14:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry
Jan-06-2021 14:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b>	Initial Entry
Nov-24-2020 15:13:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> Not Applicable	Initial Entry
Nov-16-2020 15:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> Unknown	Initial Entry
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b>	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 15:16:38	ACV0PFEINFP6000	Chelsey	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		LoMonaco (pfe.clomonaco)	FEVER	
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**4.a Was symptom present?**

Date	Location	User	Value	Reason
Jan-06-2021 14:40:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry
Jan-06-2021 14:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Initial Entry
Nov-24-2020 15:13:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-16-2020 15:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Unknown	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> NO	Initial Entry
Jan-06-2021 14:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b>	Initial Entry
Nov-24-2020 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> Not Applicable	Initial Entry
Nov-16-2020 15:16:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> Unknown	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levissc

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

Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b>	Initial Entry
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4.b Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry
Jan-06-2021 14:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Initial Entry
Nov-24-2020 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-16-2020 15:16:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Unknown	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry
Jan-06-2021 14:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

090177e196ae2f6d\Final\On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levisse

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

			<b>Symptom Present:</b>	
Nov-24-2020 15:14:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> Not Applicable	Initial Entry
Nov-16-2020 15:17:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> Unknown	Initial Entry
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b>	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1005**Subject No:** 10051293**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**4.c Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEW OR INCREASED SHORTNE SS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry
Jan-06-2021 14:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Initial Entry
Nov-24-2020 15:14:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-16-2020 15:17:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Unknown	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry
Jan-06-2021 14:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b>	Initial Entry
Nov-24-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> Not Applicable	Initial Entry
Nov-16-2020 15:17:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> Unknown	Initial Entry
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Chelsey LoMonaco	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS	Initial Entry

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History  
**Form Version:** 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Not Complete  
**Site No:** 1005 **Site Name:** (1005) Rochester Clinical Research, Inc.  
**Subject No:** 10051293 **Subject Initials:** ---  
**Generated By:** pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

(US & Canada)		(pfe.clomonaco)	<b>Symptom Present:</b>	
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**4.d Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry
Jan-06-2021 14:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Initial Entry
Nov-24-2020 15:14:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-16-2020 15:17:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Unknown	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D MUSCLE PAIN <b>Symptom</b> NO <b>Present:</b>	Initial Entry
Jan-06-2021 14:42:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D MUSCLE PAIN <b>Symptom</b> <b>Present:</b>	Initial Entry
Nov-24-2020 15:14:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D MUSCLE PAIN	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levisse

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

			<b>Symptom Present:</b> Not Applicable	
Nov-16-2020 15:17:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASE : D MUSCLE PAIN <b>Symptom Present:</b> Unknown	Initial Entry
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASE : D MUSCLE PAIN <b>Symptom Present:</b>	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry
Jan-06-2021 14:42:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Initial Entry
Nov-24-2020 15:14:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-16-2020 15:17:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Unknown	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

4.f

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TAS TE OR SMELL <b>Symptom</b> NO <b>Present:</b>	Initial Entry
Jan-06-2021 14:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TAS TE OR SMELL <b>Symptom</b> <b>Present:</b>	Initial Entry
Nov-24-2020 15:15:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TAS TE OR SMELL <b>Symptom</b> Not Applicable <b>Present:</b>	Initial Entry
Nov-16-2020 15:17:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TAS TE OR SMELL <b>Symptom</b> Unknown <b>Present:</b>	Initial Entry
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TAS TE OR SMELL <b>Symptom</b> <b>Present:</b>	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levisse

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

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMEL L	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry
Jan-06-2021 14:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Initial Entry
Nov-24-2020 15:15:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-16-2020 15:17:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Unknown	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D SORE THROAT <b>Symptom</b> NO <b>Present:</b>	Initial Entry
Jan-06-2021 14:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D SORE THROAT <b>Symptom</b> <b>Present:</b>	Initial Entry
Nov-24-2020 15:15:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D SORE THROAT <b>Symptom</b> Not Applicable <b>Present:</b>	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

Nov-16-2020 15:17:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D SORE THROAT <b>Symptom</b> Unknown <b>Present:</b>	Initial Entry
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D SORE THROAT <b>Symptom</b> <b>Present:</b>	Initial Entry

**4.g Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEW OR INCREASED SORE TH ROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry
Jan-06-2021 14:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Initial Entry
Nov-24-2020 15:15:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-16-2020 15:17:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Unknown	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry
Jan-06-2021 14:43:26 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)			Symptoms: DIARRHEA Symptom Present:	
Nov-24-2020 15:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Data Entry: Symptoms: DIARRHEA Symptom Present : Not Applicable	Initial Entry
Nov-16-2020 15:17:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptoms: DIARRHEA Symptom Present: Unknown	Initial Entry
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptoms: DIARRHEA Symptom Present:	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Data Entry: NO	Initial Entry
Jan-06-2021 14:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Data Entry:	Initial Entry
Nov-24-2020 15:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Data Entry: Not Applicable	Initial Entry
Nov-16-2020 15:17:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Unknown	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02	ACV0PFEINFP6000	Julie Mooney	Data Entry:	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1005**Subject No:** 10051293**Generated By:** pfe.levisse**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)		(pfe.jmooney)	<b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	
Jan-06-2021 14:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b>	Initial Entry
Nov-24-2020 15:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present</b> Not Applicabl e	Initial Entry
Nov-16-2020 15:18:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> Unknown	Initial Entry
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b>	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Jan-06-2021 14:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry
Jan-06-2021 14:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Initial Entry
Nov-24-2020 15:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-16-2020 15:18:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Unknown	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 15:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**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
Nov-16-2020 15:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Nov-23-2020 17:34:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> SWABBED MATERIAL	New Information
Nov-16-2020 15:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RESPIRATORY SECRETIONS	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Nov-17-2020 10:05:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 1: Closed	Response satisfies query
Nov-17-2020 08:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	specimen collection location unknown per source
Nov-17-2020 08:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 1: Opened	Per eCRF completion guidelines, if Respiratory Secretions are indicated as the Specimen Type, please select LOWER RESPIRATORY SYSTEM. Otherwise, please indicate the site of the Swab as NASOPHARYNX or THROAT.
Nov-16-2020 15:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Date	Location	User	Value	Reason
Nov-16-2020 15:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDROM E CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Nov-16-2020 15:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Nov-16-2020 15:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> OTHER	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Nov-24-2020 00:16:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Nov-23-2020 17:33:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-23-2020 17:33:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NEGATIVE	New Information
Nov-20-2020 02:18:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Reissued:Opened	DM: Please let us know when you will be able to update test results. Thank you.
Nov-19-2020 08:18:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	results are still unknown at this time
Nov-18-2020 05:00:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "Test Results" is missing. Kindly review and update.

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Nov-23-2020 17:34:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	New Information
Nov-16-2020 15:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> PENDING RESULTS	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Nov-16-2020 15:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NALT UNKNOWN	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

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
Nov-16-2020 15:20:32 (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-16-2020 15:20:32 (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
Nov-16-2020 15:20:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<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
Nov-16-2020 15:20:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNABLE TO CONTACT SUBJECT AT THIS TIME TO OBTAIN SWAB	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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
Nov-16-2020 15:21:25 (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-16-2020 15:21:25 (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
Nov-16-2020 15:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<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
Nov-16-2020 15:21:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT ABLE TO COLLECT UNABLE TO CONTACT SUBJECT AT TIME	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<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
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***I.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levisse

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

			Occurrence of Visits or Contacts: NO	
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**I.d Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> URGENT CARE	Initial Entry

**I.d Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**I.e Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

**I.e Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**I.f**

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Chelsey LoMonaco	<b>Data Entry:</b>	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(US & Canada)		(pfe.clomonaco)	<b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts :</b> YES <i>Number of Visits or Contacts:</i>  1	
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***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***2. Other Type of Practitioner Specify:***

Date	Location	User	Value	Reason
Nov-17-2020 15:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (pfe.shahr4)	Query 1: Closed	Response satisfies query
Nov-17-2020 14:27:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	updated
Nov-17-2020 14:16:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (pfe.shahr4)	Query 1: Opened	CLIQUERY: IF the subject has been hospitalized, please enter question in the line item #3 as yes and complete the HOSPITALIZATION CRF.
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> HOSPITALIZED	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

Date	Location	User	Value	Reason
Nov-24-2020 08:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikh06)	Query 2: Closed	Response satisfies query
Nov-23-2020 17:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	updated
Nov-18-2020 12:22:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikh06)	Query 2: Opened	CLINQUERY: Subject was hospitalized. Please enter on the relevant CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain this information.
Nov-17-2020 15:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (pfe.shahr4)	Query 1: Closed	Response satisfies query
Nov-17-2020 14:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-17-2020 14:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> YES Has the subject been in intensive care due to potential COVID-19 illness?  YES	Transcription Error
Nov-17-2020 14:18:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (pfe.shahr4)	Query 1: Opened	CLINQUERY: Given that the subject has been hospitalized, please update the answer to this question as appropriate.
Nov-16-2020 15:22:08 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Chelsey LoMonaco	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020      **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(US & Canada)

(pfe.clomonaco)

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** HOSPITALIZATION DETAILS - Audit Trail

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

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-17-2020 15:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

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
Nov-17-2020 15:36:11 (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
Nov-17-2020 15:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> ICU	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Nov-17-2020 16:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (pfe.shahr4)	Query 1: Closed	Response satisfies query
Nov-17-2020 15:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	HOSPITALIZATION DETAILS ARE CURRENTLY UNKNOWN AT THIS TIME
Nov-17-2020 15:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (pfe.shahr4)	Query 1: Opened	CLIQUEY: please add another row for hospitalization details (e.g admission date).
Nov-17-2020 15:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Nov-17-2020 15:36:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** RESPIRATORY TREATMENT - Audit Trail

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

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 15:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Nov-16-2020 15:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Nov-16-2020 15:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> YES	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> MECHANICAL VENTILATION	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> MECHANICAL VENTILATION	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-16-2020 15:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Nov-16-2020 15:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-16-2020 15:24:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Nov-17-2020 17:33:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.
Nov-17-2020 14:26:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answer ed	per request
Nov-17-2020 14:26:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> YES <i>Respiratory Illn ess Diagnosis:</i>  ACUTE RESP IRATORY FA ILURE  Date of Diagnos is:  Nov/8/2020	per request
Nov-17-2020 12:34:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Multiple concepts in the term ACUTE RESPIRATORY FAILURE AND OVERDOSE AND CARDIAC ARREST. Split the term into ACUTE RESPIRATORY

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

				FAILURE and OVERDOSE and CARDIAC ARREST and report as separate entries. Thank you.
Nov-17-2020 09:21:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Nov-17-2020 08:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-17-2020 08:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  ACUTE RESPIRATORY FAILURE and OVERDOSE and CARDIAC ARREST  Date of Diagnosis:  Nov/8/2020	Changed Information
Nov-17-2020 03:00:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term ACUTE RESPIRATORY FAILURE, OVERDOSE, CARDIAC ARREST. Split the term into ACUTE RESPIRATORY FAILURE and OVERDOSE and CARDIAC

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

				ARREST and report as 3 separate entries. Thank you.
Nov-16-2020 15:24:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  ACUTE RESPIRATORY FAILURE, OVERDOSE, CARDIAC ARREST  Date of Diagnosis:  Nov/8/2020	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-16-2020 15:24:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 4	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

**Form Version:** 10-Oct-2020 15:58

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Not Complete

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

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
Nov-16-2020 15:27:28 (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
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Strong Memorial Labs 601 Elmwood Avenue Rochester, NY 14642	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-16-2020 16:28:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Nov/10/2020	Transcription Error
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (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
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Identifier: Test:: C Reactive Protein_PX329 Result: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 30 <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> 64 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0 <i>High</i> 50 <i>Unit</i> U/L	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Not Complete**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (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
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Alanine Aminotransferase_PX30	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 64	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 50  <i>Unit</i> U/L	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 28 <b>Test::</b> Aspartate Aminotransferase_PX28 <b>Result::</b> 24 <b>Not Done::</b>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Not Complete

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levisse

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

			<b>Lab Normal Range:</b> <i>Low</i> 0  <i>High</i> 50  <i>Unit</i> U/L	
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (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
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Aspartate Aminotransferase_PX28	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 24	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 50  <i>Unit</i> U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 35 <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> 61 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 40  <i>High</i> 130  <i>Unit</i> U/L	Initial Entry
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Not Complete**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (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
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Alkaline Phosphatase_PX35	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 61	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 40  <i>High</i> 130  <i>Unit</i> U/L	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Mar-12-2021 12:24:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> <b>Sponsor-Defined Iden 21 tifier:</b> <b>Test::</b> Bilirubin_P X21 <b>Result::</b> 0.5 <b>Not Done::</b>	Transcription Error

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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> 1.2  <i>Unit</i> mg/dL	
Nov-16-2020 15:27:28 (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 <b>Result::</b> 0.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 1.2  <i>Unit</i> U/L	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (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
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 0.5	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Mar-13-2021 11:20:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Closed	Response satisfies query
Mar-12-2021 12:24:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-12-2021 12:24:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 1.2  <i>Unit</i> mg/dL	Transcription Error
Mar-10-2021 21:59:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Opened	Clin: The Unit entered on the CRF is not correct. Please The Unit should be "mg/dL"

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

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

Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 1.2  <i>Unit</i> U/L	Initial Entry
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5.f

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 47 <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 12 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 6  <i>High</i> 20  <i>Unit</i> mg/dL	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Not Complete**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (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
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Blood Urea Nitrogen_PX47	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 12	Initial Entry

**5.f LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 6  <i>High</i> 20  <i>Unit</i> mg/dL	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Iden</b> 48 <b>tifier:</b> <b>Test::</b> Creatinine_P X48 <b>Result::</b> 0.79 <b>Not Done::</b>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Not Complete

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levisse

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

			<b>Lab Normal Range:</b> <i>Low</i> 0.67  <i>High</i> 1.17  <i>Unit</i> mg/dL	
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5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (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
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 0.79	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-16-2020 15:27:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 0.67  <i>High</i> 1.17  <i>Unit</i> mg/dL	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

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

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

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

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Form Created	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**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
Nov-16-2020 15:31:19 (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
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Strong Memorial Labs 601 Elmwood Avenue Rochester, NY 14642	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-16-2020 16:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Nov/10/2020	Transcription Error
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (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
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: 13.7 Not Done::	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b> <i>Low</i> 13.7  <i>High</i> 17.5  <i>Unit</i> g/dL	
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**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (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
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 13.7	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 13.7  <i>High</i> 17.5  <i>Unit</i> g/dL	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hematocrit_P X2 <b>Result::</b> 41 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 40  <i>High</i> 51  <i>Unit</i> %	Initial Entry
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (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
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 41	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 40  <i>High</i> 51  <i>Unit</i> %	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 3 <b>Test::</b> Erythrocytes_PX3 <b>Result::</b> 4.6 <b>Not Done::</b>	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b> <i>Low</i> 4.6  <i>High</i> 6.1  <i>Unit</i> 10 <sup>3</sup> /uL	
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**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (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
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 4.6	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 4.6  <i>High</i> 6.1  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

**5.d**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_P X5 <b>Result::</b> 234 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 150  <i>High</i> 330  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (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
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 234	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 150  <i>High</i> 330  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Leukocytes_P X7 <b>Result::</b> 5.9 <b>Not Done::</b>	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levisse

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

			<b>Lab Normal Range:</b> <i>Low</i> 4.2  <i>High</i> 9.1  <i>Unit</i> 10 <sup>3</sup> /uL	
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5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (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
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 5.9	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 4.2  <i>High</i> 9.1  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

5.f

Date	Location	User	Value	Reason
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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**Generated By:** pfe.levisse

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

Nov-16-2020 15:31:19 (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_P X608 <b>Result::</b> 4.0 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1.8  <i>High</i> 5.4  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (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
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Neutrophils_PX608	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 4.0	Initial Entry

**5.f LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 1.8  <i>High</i> 5.4  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_P X609 <b>Result::</b> 0.2 <b>Not Done::</b>	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**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> 0.5  <i>Unit</i> 10 <sup>3</sup> /uL	
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**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (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
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 0.2	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.5  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

**5.h**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Nov-16-2020 15:31:19 (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> 0.4 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.3  <i>High</i> 0.8  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (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
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Monocytes_PX612	Initial Entry

**5.h Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 0.4	Initial Entry

**5.h LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 0.3  <i>High</i> 0.8  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

**5.i**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_PX 610 <b>Result::</b> 0.1 <b>Not Done::</b>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

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> 0.1  <i>Unit</i> 10 <sup>3</sup> /uL	
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5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (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
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 0.1	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.1  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

5.j

Date	Location	User	Value	Reason
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Nov-16-2020 15:31:19 (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_P X611 <b>Result::</b> 1.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1.3  <i>High</i> 3.6  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Lymphocytes_PX611	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 1.3	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 15:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <i>Low</i> 1.3  <i>High</i> 3.6  <i>Unit</i> 10^3/uL	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Strong Memorial Labs 601 Elmwood Avenue Rochester, NY 14642	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: 15 Not Done::	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b> <i>Low</i> 13.7  <i>High</i> 17.5  <i>Unit</i> g/dL	
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**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 15	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <i>Low</i> 13.7  <i>High</i> 17.5  <i>Unit</i> g/dL	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hematocrit_P X2 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Erythrocytes_ PX3 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-16-2020 16:34:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_P X5 <b>Result::</b> 303 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 150  High 330  Unit 10^3/uL	Transcription Error
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_P X5	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Result::</b> 303	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			150	
			<i>High</i>	
			330	
			<i>Unit</i>	
			/uL	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 303	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 16:34:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <i>Low</i> 150  <i>High</i> 330  <i>Unit</i> 10 <sup>3</sup> /uL	Transcription Error
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <i>Low</i> 150  <i>High</i> 330  <i>Unit</i> /uL	Initial Entry

**5.e**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levisse

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

Nov-16-2020 16:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Leukocytes_ PX7 <b>Result::</b> 11.2 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.2  <i>High</i> 9.1  <i>Unit</i> 10^3/uL	Transcription Error
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Leukocytes_ PX7 <b>Result::</b> 11.2 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.2  <i>High</i> 9.1  <i>Unit</i> /uL	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051293**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 11.2	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Nov-16-2020 16:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <i>Low</i> 4.2  <i>High</i> 9.1  <i>Unit</i> 10 <sup>3</sup> /uL	Transcription Error
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <i>Low</i> 4.2  <i>High</i> 9.1  <i>Unit</i> /uL	Initial Entry

**5.f**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Nov-16-2020 16:33:49 (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_P X608 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry
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**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Neutrophils_PX608	Initial Entry

**5.f Not Done:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_P X609 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Monocytes_PX612	Initial Entry

**5.h Not Done:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.i**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Iden 610 tifier: Test:: Basophils_PX 610 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (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
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 611 <b>entifier:</b> <b>Test::</b> Lymphocytes_ PX611 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Lymphocytes_PX611	Initial Entry

**5.j Not Done:**

Date	Location	User	Value	Reason
Nov-16-2020 16:33:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail  
Nov/09/2020

**Form Version:** 10-Oct-2020 15:59

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-23-2020 17:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail  
Nov/09/2020

**Form Version:** 10-Oct-2020 15:59

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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[Back to Form](#)

Date	Location	User	Value	Reason
Feb-17-2021 07:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Form Deleted	Transcription Error
Nov-23-2020 17:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Form Created	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
Nov/09/2020

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

**I. Date:**

Date	Location	User	Value	Reason
Feb-17-2021 11:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe.francm73)	Query 2: Closed	Response satisfies query
Feb-17-2021 07:42:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	Changed data per query
Feb-17-2021 04:24:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 2: Opened	Check all assessments performed on 08Nov2020. If multiple values were recorded on a single day, only the most abnormal should be recorded, i.e. the lowest Diastolic & Systolic BP and the highest Heart Rate & Respiratory rate. Please check and update.
Feb-08-2021 03:33:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 1: Closed	Response satisfies query
Feb-07-2021 11:38:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	CORRECT AS IS PER SOURCE
Feb-04-2021 02:45:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	Check all assessments performed on 08Nov2020. If multiple values were recorded on a single day, at a minimum the most abnormal should be recorded, i.e. the lowest Diastolic & Systolic Blood Pressure and the highest Heart Rate & Respiratory

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levisse

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

				rate
Nov-23-2020 17:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-23-2020 17:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 13 9 <b>Diastolic::</b> 88 <b>Respiratory Rate in respiratio ns/minute:</b> 14 <b>Heart Rate in beats/minute:</b> 11 4	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-23-2020 17:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-23-2020 17:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 139	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Nov-23-2020 17:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 88	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-23-2020 17:39:46 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 14	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(US & Canada)

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Nov-23-2020 17:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 114	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levissc

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

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[Back to Form](#)

I. Date:

Date	Location	User	Value	Reason
Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> Not Applicable	Initial Entry
Feb-17-2021 07:41:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u>	Transcription Error
Nov-23-2020 17:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> Nov/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> <b>Record Identifier::</b> 1 <b>Systolic::</b> Not Applicable <b>Diastolic::</b> Not Applicable <b>Respiratory Rate in respirations/minute:</b> Not Applicable <b>Heart Rate in beats/minute:</b> Not Applicable	Initial Entry
Feb-17-2021 07:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> <b>Record Identifier::</b> 1 <b>Systolic::</b> <b>Diastolic::</b> <b>Respiratory Rate in respirations/minute:</b> <b>Heart Rate in beats/minute:</b>	Transcription Error
Nov-23-2020 17:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> <b>Record Identifier::</b> 1 <b>Systolic::</b> 13 6 <b>Diastolic::</b> 88	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Deleted

Site No: 1005

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Subject Initials: ---

Generated By: pfe.levisse

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

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			Respiratory Rate in respirations/minute: 22	
			Heart Rate in beats/minute: 109	

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-23-2020 17:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> Not Applicable	Initial Entry
Feb-17-2021 07:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u>	Transcription Error
Nov-23-2020 17:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> 136	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> Not Applicable	Initial Entry
Feb-17-2021 07:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u>	Transcription Error
Nov-23-2020 17:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> 88	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
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090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
Nov/09/2020

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Deleted

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-17-2021 07:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Transcription Error
Nov-23-2020 17:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 22	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Feb-25-2021 08:26:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-17-2021 07:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Transcription Error
Nov-23-2020 17:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 109	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail

**Form Version:** 10-Oct-2020 16:04

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-23-2020 17:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail  
Nov/09/2020

**Form Version:** 10-Oct-2020 16:04

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-25-2021 08:28:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Form Deleted	New Information
Nov-23-2020 17:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Form Created	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:04

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**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

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**Generated By:** pfe.levisse

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

[Back to Form](#)

**I. Date:**

Date	Location	User	Value	Reason
Feb-25-2021 12:26:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Elizabeth Chatburn (pfe.chatbe)	Query 1: Closed	duplicate data removed
Feb-25-2021 08:28:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	Changed data per query
Feb-17-2021 11:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe.francm73)	Query 1: Reissued:Opened	DM: Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded, i.e. the lowest Oxygen Saturation for the day. Please review all data entered on 08Nov2020 and remove as applicable. Else clarify.
Feb-17-2021 07:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	Changed data per query
Feb-17-2021 04:22:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded, i.e. the lowest Oxygen Saturation for the day. Please review all data entered on 08Nov2020 and remove as applicable. Else clarify.
Nov-23-2020 17:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1005

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**Generated By:** pfe.levisse

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

**2.a**

Date	Location	User	Value	Reason
Nov-23-2020 17:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 95.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-23-2020 17:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Nov-23-2020 17:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 95.0	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History  
Nov/09/2020

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Data Complete, Deleted

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.leviscc

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

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

[Back to Form](#)

**I. Date:**

Date	Location	User	Value	Reason
Nov-23-2020 17:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-23-2020 17:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 100.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-23-2020 17:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Nov-23-2020 17:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 100.0	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** OXYGENATION PARAMETERS - Audit Trail

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

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 15:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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-16-2020 15:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/8/2020 UNK:UNK	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Nov-16-2020 15:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 80	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Nov-16-2020 15:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Unknown	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Audit Trail  
Nov/09/2020

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

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 15:32:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** IMAGING - Audit Trail

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

**Form Status:**

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 15:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History  
Nov/09/2020

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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
Nov-16-2020 15:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/8/2020	Transcription Error
Nov-16-2020 15:32:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/9/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:32:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> HEAD	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Nov-16-2020 15:32:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> CT SCAN	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:32:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NORMAL	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** IMAGING - eCRF Audit Trail History

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/8/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> CHEST	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Nov-16-2020 15:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> X-RAY	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Nov-16-2020 15:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> ABNORMAL <i>If abnormal, specify findings:</i>  Bilateral perihilar airspace & interstitial opacities -possible pulmonary edema vs. infection	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

**Form Status:**

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

**Form Status:**

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Form Created	

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

**Form Status:**

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-09-2020 17:18:46 (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-09-2020 17:18:46 (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-11-2020 21:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Nov-11-2020 21:53:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-11-2020 14:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	On CRF as overdose
Nov-11-2020 14:50:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	CRF listed as acute respiratory failure per hospital records
Nov-10-2020 20:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - SAE report also notes an event of multidrug use including cocaine; please review for safety impact, and report on AE CRF if applicable.
Nov-10-2020 20:48:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - SAE report (#2020443745) also reports SAE of 'pulmonary edema or infection'. Please

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

				report this event on AE CRF as well.
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> CARDIAC ARREST	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Nov/8/2020 00:43	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 11:57:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-16-2020 11:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-16-2020 11:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO End Date Time:  Nov/8/2020 UNK:UNK	Changed Information
Nov-15-2020 14:30:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - Stop date for event of Cardiac Arrest has not been entered; however, OD on 08Nov2020 was successfully resuscitated. Please review, and assess for conclusion of this event. If updated, please submit a SAE update with end date
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<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-10-2020 10:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 1: Closed	Response satisfies query
Nov-10-2020 09:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	SAE faxed to pfizer yesterday 11/9 at 4:30pm
Nov-10-2020 08:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: CARDIAC ARREST Onset date:08Nov2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE CARDIAC ARREST: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051293

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

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

			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?	
			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.*

Date	Location	User	Value	Reason
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 11:19:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 2: Closed	AS per site clarification.
Nov-12-2020 01:11:35 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Closed	Closed as data updated.

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

(US & Canada)				
Nov-11-2020 14:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	Overdose SAE added to CRF
Nov-11-2020 14:33:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	Subject did not report history of substance abuse at Visit 1.
Nov-11-2020 10:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 2: Opened	GPDCLIN: Please clarify if any history of substance abuse and if yes, please update Medical history page as applicable.
Nov-11-2020 06:56:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [intentional overdose]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[suryas18 SDQ=45307]"
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051293

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

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

				OTHER  If Other, specify:  possible intentional overdose, or poor choice of alcohol and drug abuse.
--	--	--	--	---

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-11-2020 15:34:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 1: Closed	Response satisfies query
Nov-11-2020 14:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-11-2020 14:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> YES	New Information
Nov-11-2020 09:32:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 1: Opened	Per source, subject received Narcan. Please review and confirm if this should be updated to "yes" and if so update CRF accordingly, otherwise clarify.
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051293

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 11:27:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-16-2020 11:27:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> RECOVERED/RESOLVED	Changed Information
Nov-16-2020 11:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE CARDIAC ARREST: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-10-2020 16:16:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_AE001_35
Nov-10-2020 09:14:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-10-2020 09:14:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RECOVERING/RESOLVING	Transcription Error

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

Canada)			G	
Nov-10-2020 08:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW5336757;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RECOVERED/RESOLVED WITH SEQUELAE	Initial Entry

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

Date	Location	User	Value	Reason
Nov-09-2020 17:18:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Nov-12-2020 04:35:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020443745	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levisse

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

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**Subject Initials:** ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 14:49:01 (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-11-2020 14:49:01 (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
Dec-15-2020 12:58:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Site clarified that unknown Hosp discharge date is due to inability to contact subject
Dec-15-2020 07:29:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	Dates of hospitalization are already included in original SAE form. Unknown if subject has been discharged at this time as site has been unsuccessful in multiple attempts to reach subject.
Dec-09-2020 10:04:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Please submit a SAE safety followup reporting the dates of hospitalization. If discharged, please consider end date for EVENT of acute respiratory failure.
Nov-16-2020 19:02:37 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Salim Bouguermouh	Query 1: Closed	Response satisfies query

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

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Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

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

(US & Canada)		(pfe.bogus)		
Nov-16-2020 16:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	COVID visit completed
Nov-13-2020 15:56:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Opened	Clin: Per protocol section 8.1., potential COVID-19 related ACUTE RESPIRATORY FAILURE should have please triggered a COVID Illness Visit irrespective of perceived etiology or clinical significance and a nasal swab collected ASAP.
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Acute Respiratory Failure	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Nov/8/2020 00:43	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-07-2021 00:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 3: Closed	Response satisfies query
Jan-06-2021 14:48:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 3: Answered	Original value is correct
Jan-06-2021 14:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1005**Subject No:** 10051293**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-05-2021 13:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teresa Vu (pfe.vut11)	Query 2: Closed	Response satisfies query
Jan-05-2021 07:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.
Nov-24-2020 23:18:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-24-2020 15:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	unknown end date at this time
Nov-24-2020 11:42:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Please review event of Acute Respiratory Failure for resolution and end date
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<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-24-2020 23:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Closed	Query closed; will follow for SAE update with the requested COVID test info

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

Nov-24-2020 15:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 5: Answered	Will submit updated SAE form today
Nov-24-2020 11:45:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Opened	Clinical - Followup for COVID test in Hosp on 08Nov2020; please submit test result in a SAE (#2020443745) safety update
Nov-16-2020 15:18:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Query closed; will follow for SAE update with the requested COVID test info
Nov-16-2020 14:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 4: Answered	Results still unknown at this time - site trying to obtain results - will update once completed
Nov-15-2020 14:33:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	CLINICAL - SAE update on 12Nov20 included COVID test performance on 08Nov20; however, the result was pending. Please submit a SAE safety update with the noted COVID test result
Nov-13-2020 11:35:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Nov-13-2020 08:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Nov-12-2020 10:07:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	covid test listed under Relevant Tests in the SAE form that was faxed on 11.11.2020
Nov-12-2020 10:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 3: Answered	SAE EVENT section was completed and faxed on 11.11.2020 for Acute Respiratory Failure

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1005**Subject No:** 10051293**Generated By:** pfe.lewissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Nov-12-2020 04:41:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Nov-11-2020 18:50:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL - as event of Acute Respiratory Failure is a SAE, please submit a SAE followup form reporting this in the SAE EVENT section
Nov-11-2020 18:42:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2020443745] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Acute Respiratory Failure: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> 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	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051293

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

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

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

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

Date	Location	User	Value	Reason
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 06:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 2: Closed	Per site no further information as subject is LTFU.
Jan-21-2021 14:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	Unable to further clarify as subject is a lost to follow up
Jan-12-2021 15:05:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaard)	Query 2: Opened	GPDCLIN: Other cause for of Acute Respiratory Failure event is unknown; Please advise if the cause/causes for this AE can be further clarified & update as appropriate. Else, please clarify.
Jan-12-2021 06:30:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 2: Candidate	GPDCLIN: Other cause for of Acute Respiratory Failure

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1005**Subject No:** 10051293**Generated By:** pfe.lewissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

				event is unknown; Please advise if the cause/causes for this AE can be further clarified & update as appropriate. Else, please clarify.
Jan-12-2021 06:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	frozen page. need to re-issue in a candidate state to allow site updates if needed.
Jan-12-2021 06:29:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Other cause for of Acute Respiratory Failure event is unknown; Please advise if the cause/causes for this AE can be further clarified & update as appropriate. Else, please clarify.
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	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, Verified

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 06:14:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Per site no further information as subject is lost to FU.
Jan-21-2021 14:47:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	Unable to determine end date as subject is a lost to follow up
Jan-12-2021 15:06:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Opened	GPDCLIN: Acute respiratory failure Grade 4 is listed a ongoing with an outcome of RECOVERING/RESOLVING. Was there a change in grade? Please review event for resolution and end date.
Jan-12-2021 06:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Candidate	GPDCLIN: Acute respiratory failure Grade 4 is listed a ongoing with an outcome of RECOVERING/RESOLVING. Was there a change in grade? Please review event for resolution and end date.

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Nov-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<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-11-2020 14:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Nov-12-2020 13:13:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	<b>Data Entry:</b> 2020443745	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levisse

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 14:51:50 (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-11-2020 14:51:50 (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
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Overdose	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Nov/8/2020 00:43	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 11:57:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Nov-16-2020 11:26:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-16-2020 11:26:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO End Date Time:  Nov/8/2020 UNK:UNK	Changed Information

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

Nov-15-2020 14:29:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - Stop date for event of Overdose has not been entered; however, OD on 08Nov2020 was successfully resuscitated. Please review, and assess for conclusion of this event. If updated, please submit a SAE update with end date
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<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-16-2020 15:19:33 (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 event date info
Nov-16-2020 14:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 3: Answered	Updated SAE form emailed to safety at 1442 today.
Nov-16-2020 11:59:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	Clinical - Thank you. Please include the end dates for events Cardiac arrest and OD as well in the SAE safety update.

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

<b>Header Text:</b> c4591001 <b>Visit:</b> Logs - Unscheduled <b>Form Version:</b> 22-Apr-2020 21:02 <b>Site No:</b> 1005 <b>Subject No:</b> 10051293 <b>Generated By:</b> pfe.levissc				
<b>Form:</b> ADVERSE EVENT REPORT - eCRF Audit Trail History <b>Form Status:</b> Data Complete, Frozen, Not Complete <b>Site Name:</b> (1005) Rochester Clinical Research, Inc. <b>Subject Initials:</b> --- <b>Generated Time (GMT):</b> 29-Mar-2021 04:04				
Nov-16-2020 11:25:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 3: Answered	Narcan was used in resuscitation. Intentionality of multidrug OD is still unavailable at this time. Updated SAE form will be submitted today with Narcan and intentionality unknown in narrative section.
Nov-13-2020 08:11:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL Please provide clinical f/u as to use of Narcan in resuscitation and the question as to intentionality in the multidrug OD
Nov-12-2020 13:33:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Nov-12-2020 10:04:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	SAE EVENT section was completed and faxed on 11.11.2020 for Overdose.
Nov-12-2020 04:42:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Deleted	Query can be addressed internally
Nov-11-2020 18:51:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL - as event of Overdose is a SAE, please submit a SAE followup form reporting this in the SAE EVENT section
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Overdose: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> YES Is this serious event associated wit	Initial Entry



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051293

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

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

			<p>h 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 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-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-22-2021 23:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-22-2021 12:55:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1005**Subject No:** 10051293**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-22-2021 12:55:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  multi-drug ingestion	Changed Information
Jan-12-2021 15:07:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Opened	Clinical Other cause for Overdose event is unknown; however, SAE reports multiple exposures (ingestion of alcohol, gabapentin, narcotic analgesic; cocaine on urine tox screen). Please consider Other reason for Overdose event, & update as appropriate
Jan-11-2021 15:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Candidate	Clinical Other cause for Overdose event is unknown; however, SAE reports multiple exposures (ingestion of alcohol, gabapentin, narcotic analgesic; cocaine on urine tox screen). Please consider Other reason for Overdose event, & update as appropriate
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown	Initial Entry

**10. Latest Action Taken with Study Treatment:**

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 11:26:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-16-2020 11:26:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> RECOVERED/RESOLVED	Changed Information
Nov-16-2020 11:26:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Overdose: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<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-11-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.lewissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

*15. Serious Adverse Event Number: For Pfizer Use Only*

Date	Location	User	Value	Reason
Nov-12-2020 13:14:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	<b>Data Entry:</b> 2020443745	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1005

Site Name: (1005) Rochester Clinical Research, Inc.

Subject No: 10051293

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Mar-01-2021 07:57:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rose Madelein (pfe.roseml9)	Query 2: Closed	Response satisfies query
Feb-27-2021 15:59:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	V2 was not completed.
Feb-22-2021 13:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (pfe.rosenr16)	Query 2: Opened	DM: Subject was considered lost to followup on 14-Dec-2020 but was scheduled for the V2_VAX2_L visit on 11-Nov-2020. Please confirm that this visit was not completed and update data as necessary.
Feb-16-2021 17:44:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Feb-16-2021 12:43:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-16-2021 12:43:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Dec/14/2020	Transcription Error
Feb-11-2021 15:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Opened	CLINQUERY: Date of EOT (for lost to follow up) is the same as visit 1. Disp FUP also reports status of LTFU but the date differs to EOT. Please review date entered and update, as appropriate
Feb-11-2021 12:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Candidate	CLINQUERY: Date of EOT (for lost to follow up) is the same

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Form Version:** 10-Dec-2020 02:29

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

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

				as visit 1. Disp FUP also reports status of LTFU but the date differs to EOT. Please review date entered and update, as appropriate
Dec-28-2020 14:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-28-2020 14:15:23 (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
Jan-06-2021 19:21:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 2: Closed	Response satisfies query
Jan-05-2021 07:16:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 2: Answered	ADDED PER REQUEST
Jan-04-2021 18:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 2: Opened	ClinQuery: Per EOT CRF page patient is lost to follow up. Please complete FUP CRF page.
Dec-28-2020 14:15:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-28-2020 14:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is LOST TO FOLLOW-UP but "Specify Status" is missing.
Dec-28-2020 14:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> LOST TO FOLLOW-UP	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

**4. Specify Status:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-28-2020 14:16:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> SUBJECT IS LOST TO FOLLOW UP	Transcription Error
Dec-28-2020 14:15:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> SUBJET IS LOST TO FOLLOW U P	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:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**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 11:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Mar-12-2021 11:21:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Applicable	Initial Entry



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete

**Site No:** 1005

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject No:** 10051293

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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 11:21:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1005

Subject No: 10051293

Generated By: pfe.levissc

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1005) Rochester Clinical Research, Inc.

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-06-2021 14:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> Dec/14/2020	Transcription Error
Jan-05-2021 07:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-05-2021 07:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-05-2021 07:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-05-2021 07:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is LOST TO FOLLOW-UP but "Specify Status" is missing.
Jan-05-2021 07:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> LOST TO FOLLOW-UP	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Jan-05-2021 07:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> LOST TO FOLLOW UP	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Mar-12-2021 11:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Mar-12-2021 11:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1005**Subject No:** 10051293**Generated By:** pfe.levissc**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Mar-11-2021 03:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajalakshmi Arumugam (pfe.arumur02)	Query 1: Closed	Response satisfies query
Mar-10-2021 15:26:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Query 1: Answered	V2 marked as not done
Mar-02-2021 01:17:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kirubakaran Kesavan Kendhapedi (pfe.kendak01)	Query 1: Opened	DM: Visit 2 is overdue based on expected visit window. If visit 2 will never occur, please mark Date of Visit as 'Not Done' with form level comment.
Jan-05-2021 07:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Dec-28-2020 14:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-19-2020 11:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-19-2020 10:58:52 (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
Feb-16-2021 12:43:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/14/2020	Transcription Error
Jan-06-2021 14:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/14/2020	Transcription Error

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

**Form Status:** Data Complete, Verified

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

Jan-05-2021 07:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/19/2020	Initial Entry
Dec-28-2020 14:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/19/2020	Initial Entry
Oct-19-2020 11:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/19/2020	Initial Entry
Oct-19-2020 10:58:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/19/2020	Initial Entry

090177e196ae2f6d\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051293

**Generated By:** pfe.levissc

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

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

**Site Name:** (1005) Rochester Clinical Research, Inc.

**Subject Initials:** ---

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

[Back to Form](#)

*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-17-2020 15:41:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Click Here to Enable	Initial Entry