

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/12/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10031186]
2.	Birth Date:	(b) (6) /1987
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:	

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Aug/12/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

[Form Comments](#)

**Inclusion Criteria Not Met**

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

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

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** DISPOSITION - SCREENING

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Aug/12/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[narcolepsy]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[hypothyroid]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[obesity]
	Start Date:	UNK/UNK/2020
	Ongoing:	YES

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/12/2020
2.	Weight:	[315.0]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[42.7]

**Vital Signs Details**

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



**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** RANDOMIZATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/12/2020
2.	Randomization Number:	[47001]
3.	Randomization Group:	[ ]

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031186**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	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/12/2020
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	[BP579G]
5.b	Sample ID	[BP579H]
5.c	Sample ID	[BP579J]
5.d	Sample ID	[BKDZ3X]
5.e	Sample ID	[BKDZ3Y]

**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/12/2020
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	[BP57B6]
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**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/12/2020 10:03
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

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** REACTOGENICITY DIARY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Sep/3/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/3/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
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	[BP57LR]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/3/2020 09:47
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

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Oct/7/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[low draw]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYL9N]
5.b	Sample ID	[BNWKJW]

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/14/2020
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 Dec/14/2020

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Dec/14/2020
2.	Date of First Symptom Started:	Dec/12/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/24/2020

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	YES
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	YES
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
<b>Symptoms - Other</b>		
5.	Symptoms - Other Text:	[ ]

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** MICROBIOLOGY SPECIMEN

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

**Form Status:** Data Complete

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Microbiology Specimen**

1.	Actual Date of Collection:	Dec/14/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	ROCHE MOLECULAR SYSTEMS COBAS SARS-COV-2
7.	Test Result:	POSITIVE
8.	Comments/Findings /Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

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

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Dec/14/2020
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	[CV29503]
-----	-----------	-----------

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital**Subject No:** 10031186**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[subject completed self-swab]

**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 Dec/14/2020

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Data Complete

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**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

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Data Complete

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

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

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Respiratory Treatment**

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

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** ILLNESS DETAILS

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

**Form Status:** Data Complete

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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: [COVID-19]  Date of Diagnosis: Dec/14/2020
3.	Toxicity Grade:	3

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**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Subcategory of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
3.	Was a diagnosis obtained?	Not Applicable _____	<a href="#">Comments</a>
4.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

#	Category f or Lab Tes t	Vendor Name	Collecti on Date :	Specim en Typ e	Lab Result			Form Insta nce
1.	Not Applic able	Not Ap plicable	Not App licable	Not Ap plicable	<b>Sponsor-Def ined Identifi er</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applica ble	Not Ap plicable	Not Ap plicable	
					Not Applica ble	Not Ap plicable	Not Ap plicable	
					Not Applica ble	Not Ap plicable	Not Ap plicable	
					Not Applica ble	Not Ap plicable	Not Ap plicable	
					Not Applica ble	Not Ap plicable	Not Ap plicable	
					Not Applica ble	Not Ap plicable	Not Ap plicable	
					Not Applica ble	Not Ap plicable	Not Ap plicable	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Lab Chemistry Details**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.f	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

5.g	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

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**Header Text:** c4591001

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Laboratory Data Hematology**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

5.f	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.g	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.h	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

5.i	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

5.j	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	Not Applicable	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** VITAL SIGNS - COVID

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Vital Signs**

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

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	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>

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**Header Text:** c4591001

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	<b>Record Identifier:</b> Not Applicable	<b>Oxygen Saturation</b> Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Vital Signs**

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

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Oxygenation Parameters**

1.	Date Time of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Site No:** 1003

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

**Subject No:** 10031186

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** IMAGING

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Imaging**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Location of Assessment:	Not Applicable _____	<a href="#">Comments</a>
3.	Type of Imaging Exam:	Not Applicable _____	<a href="#">Comments</a>
4.	Assessment:	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/15/2021

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**Date of Visit**

1.	Date of Visit	Jan/15/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/15/2021

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/15/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYLJV]
5.b	Sample ID	[BNWKVG]
5.c	Sample ID	[BNWKVH]

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**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled **Form:** DATE OF VISIT  
Visit

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

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186 **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:** 1003    **Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186    **Subject Initials:** ---

**Generated By:** pfe.levissc    **Generated Time (GMT):** 29-Mar-2021 04:04

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/7/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started

**Site No:** 1003 **Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186 **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:** 1003

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

**Subject No:** 10031186

**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	Exposure During partner Pregnancy	Sep/17/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure During partner Pregnancy]	
4.	Start Date Time:	Sep/17/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Partner became Pregnant]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

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

**Form Status:** Data Complete

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Medication Error**

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

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**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Concomitant Medications**

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**Concomitant Medications**

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

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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?	

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1003

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

**Subject No:** 10031186

**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>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031186

**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:	

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001**Visit:** Unplanned Vaccination -  
Unscheduled**Form:** VACCINATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Not Started**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital**Subject No:** 10031186**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?	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Contact Outcome**

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



**Header Text:** c4591001

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

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003      **Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186      **Subject Initials:** ---

**Generated By:** pfe.levissc      **Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/8/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003      **Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186      **Subject Initials:** ---

**Generated By:** pfe.lewissc      **Generated Time (GMT):** 29-Mar-2021 04:04

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/8/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031186

**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:	[ ]

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/19/2021
----	--------------	--

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Form Comments](#)

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Jan/19/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031186**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYLK2]
5.b	Sample ID	[BNWKVR]
5.c	Sample ID	[BNWKVS]

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/19/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/19/2021 10:38
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** DATE OF VISIT

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/9/2021
2.	Erroneous Visit	

**Header Text:** c4591001**Visit:** V102\_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031186**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/9/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/9/2021 09:05
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form:** DATE OF VISIT

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

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



**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** CONTACT OUTCOME

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/11/2021
3.	Comments:	[ ]

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levisse

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

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

**Form:** DISPOSITION - TREATMENT

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Mar/11/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/7/2020

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-13-2020 09:39:39 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
2	Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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Item	Date	User	Comment
3	Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

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**Generated By:** pfe.levisse

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Item	Date	User	Comment
4	Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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Item	Date	User	Comment
5	Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable



**Header Text:** c4591001

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Item	Date	User	Comment
6	Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
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**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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Item	Date	User	Comment
Form	Jan-15-2021 09:43:22 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** ILLNESS DETAILS - SEVERE - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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**Subject No:** 10031186

**Subject Initials:** ---

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Item	Date	User	Comment
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**Form:** ILLNESS DETAILS - SEVERE - Comments

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

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Item	Date	User	Comment
5.b	Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable



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Unscheduled Visit on Dec/14/2020

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Item	Date	User	Comment
5.c	Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
5.f	Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

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**Site Name:** (1003) Rochester Regional HealthRochester  
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Item	Date	User	Comment
5.f	Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
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**Form:** VITAL SIGNS - COVID - Comments

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

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Item	Date	User	Comment
Form	Jan-15-2021 09:44:19 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

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**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** VITAL SIGNS - PULSE OX ROOM AIR -  
Comments

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

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Item	Date	User	Comment
Form	Jan-15-2021 09:44:33 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

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**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** OXYGENATION PARAMETERS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
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**Subject No:** 10031186

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Form	Jan-15-2021 09:44:51 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** OXYGENATION PARAMETERS - Comments

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**Site No:** 1003

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Item	Date	User	Comment
5	Jan-15-2021 09:45:06 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levisse

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - Comments

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6	Jan-15-2021 09:45:06 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
Form	Jan-15-2021 09:45:20 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
1	Jan-15-2021 09:45:20 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
2	Jan-15-2021 09:45:20 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
3	Jan-15-2021 09:45:20 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
4	Jan-15-2021 09:45:20 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Comments

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

**Form Status:** Data Complete

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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Item	Date	User	Comment
6	Feb-15-2021 07:11:42 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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Item	Date	User	Comment
Form	Jan-21-2021 11:20:33 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
Madison Murphy	N/A	Feb-09-2021 15:36:16 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**  
N/A

Edward Walsh	Approved	Jan-21-2021 21:28:27 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	--	------	--------

**Affidavit:**

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

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

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

Lauren Mitchell	N/A	Dec-14-2020 10:58:05 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Affidavit:**

N/A

Edward Walsh	Approved	Oct-20-2020 19:50:25 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

Marie Francis	N/A	Oct-07-2020 09:23:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Edward Walsh	Approved	Sep-11-2020 14:29:42 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Affidavit:**

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

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-12-2020 10:03:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 10:03:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> STAGE 3 COHORT S	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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*1. Consent Was:*

Date	Location	User	Value	Reason
Aug-12-2020 10:03:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> OBTAINED Date Written Cons ent Obtained  Aug/12/2020	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-12-2020 10:03:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10031186	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-12-2020 10:03:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) /1987	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-12-2020 10:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Aug-12-2020 10:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Aug-12-2020 10:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

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

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-12-2020 10:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Aug/12/2020	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

Date	Location	User	Value	Reason
Aug-12-2020 10:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Aug/12/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-12-2020 10:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-12-2020 10:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1003**Subject No:** 10031186**Generated By:** pfe.lewissc**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Aug-12-2020 10:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH N 1 umber: Medical His narcolep tory Term: sy Start Date: UNK/U NK/201 0 Ongoing: YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-12-2020 10:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

*1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Aug-12-2020 10:09:05 (UTC-05:00)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> narcolepsy	Initial Entry

**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, Locked, Frozen, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Eastern Time (US & Canada)

**1.a Start Date:**

Date	Location	User	Value	Reason
Aug-12-2020 10:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Aug-12-2020 10:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Aug-12-2020 10:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 2</b> <b>umber:</b> <b>Medical His hypothy</b> <b>tory Term: oid</b>	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

			<b>Start Date:</b> UNK/U NK/200 9	
			<b>Ongoing:</b> YES	

**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, Locked, Frozen, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-12-2020 10:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 10:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> hypothyroid	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-12-2020 10:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> UNK/UNK/2009	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Aug-12-2020 10:09:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry
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*I.c*

Date	Location	User	Value	Reason
Feb-16-2021 14:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 3</b> <b>umber:</b> <b>Medical His</b> obesity <b>tory Term:</b> <b>Start Date:</b> UNK/U NK/202 0 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

***I.c Line/MH Number:***

Date	Location	User	Value	Reason
Feb-16-2021 14:01:43 (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
Feb-16-2021 14:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> obesity	Initial Entry

***I.c Start Date:***

Date	Location	User	Value	Reason
Feb-22-2021 15:16:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 1: Closed	Response satisfies query
Feb-22-2021 08:28:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	Yes prior to vaccination

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Feb-16-2021 23:55:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Reissued: Opened	DM: Please confirm historical condition is prior to vaccination or else clarify. Thank you.
Feb-16-2021 14:02:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	Original value is correct
Feb-16-2021 14:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 12/Aug /2020. Please review and update as appropriate.
Feb-16-2021 14:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

***I.c Ongoing:***

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (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, Locked, Frozen, Verified

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Feb-16-2021 14:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry
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**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**1. Date:**

Date	Location	User	Value	Reason
Aug-12-2020 10:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Aug/12/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-13-2020 03:28:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Response satisfies query
Aug-12-2020 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	Original value is correct
Aug-12-2020 10:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Weight 315 is outside of Normal Range 25 - 136 for kg or 50 - 300 for

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

				lb.
Aug-12-2020 10:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 315.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-12-2020 10:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-12-2020 10:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 72.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-12-2020 10:15:20 (UTC-05:00)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> in	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031186

Subject Initials: ---

Generated By: pfe.levisse

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

Eastern Time (US & Canada)

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-12-2020 10:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 42.7	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-12-2020 10:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Record Identifier:</b> <b>Temperature:</b> 97.4 <b>Temperature Unit:</b> <b>Temperature Location:</b> FORE HEAD ::	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-12-2020 10:15:20	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00)  
Eastern Time (US  
& Canada)

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-12-2020 10:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 97.4	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-12-2020 10:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-12-2020 10:15:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-12-2020 10:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Aug/12/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-12-2020 10:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> 47001	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-12-2020 10:09:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-12-2020 10:09:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-12-2020 15:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-12-2020 10:09:54	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031186**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-12-2020 10:09:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES Date of Collection :  Aug/12/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-12-2020 15:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BP579 <b>D:</b> G	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-12-2020 15:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BP579G	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:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.b**

Date	Location	User	Value	Reason
Aug-12-2020 15:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BP579 <b>D:</b> H	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-12-2020 15:51:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BP579H	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-12-2020 15:51:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample ID</b> BP579 : J	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-12-2020 15:51:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BP579J	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-12-2020 15:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BKDZ3 <b>D:</b> X	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-12-2020 15:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BKDZ3X	Initial Entry

**5.e**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Aug-12-2020 15:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BKDZ3 <b>D:</b> Y	Initial Entry
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**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-12-2020 15:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BKDZ3Y	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-12-2020 10:10:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-12-2020 10:10:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-12-2020 16:03:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-12-2020 10:10:04	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031186**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-12-2020 10:10:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES Date of Collection :  Aug/12/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-12-2020 16:03:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BP57B <b>D:</b> 6	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-12-2020 16:03:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BP57B6	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Aug-12-2020 10:53:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-12-2020 10:53:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-12-2020 10:53:54 (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
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Aug-12-2020 10:53:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Aug/12/2020 10:03	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-12-2020 10:53:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-12-2020 10:53:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Aug-12-2020 10:53:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-12-2020 10:53:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 10:53:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-12-2020 10:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES - REACTOGE NICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-03-2020 09:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital**Subject No:** 10031186**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  <b>Were fever or sy N</b> <b>stemic symptom O</b> <b>s present on the</b> <b>last day the Subj</b> <b>ect Diary was co</b> <b>mpleted?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> FEVER	Initial Entry
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**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E  <b>Were fever or sy N</b> <b>stemic symptom O</b> <b>s present on the</b> <b>last day the Sub</b> <b>ject Diary was c</b> <b>ompleted?:</b>	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**2.b Symptom:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Sep-03-2020	ACV0PFEINFP6000	Emily	<b>Data Entry:</b>	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

09:20:29 (UTC-05:00) Eastern Time (US & Canada)		Pierce (pfe.epierce)	<b>Symptom::</b> C HI L LS  <b>Were fever or sy N stemic symptom O s present on the last day the Sub ject Diary was c ompleted?:</b>	
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**2.d Symptom:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG  <b>Were fever or s</b> NO <b>ystemic sympto</b> <b>ms present on t</b> <b>he last day the</b> <b>Subject Diary</b> <b>was completed?</b>  :	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**2.e Symptom:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Sep-03-2020	ACV0PFEINFP6000	Emily	<b>Data Entry:</b>	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

09:20:29  
(UTC-05:00)  
Eastern Time (US  
& Canada)

Pierce  
(pfe.epierce)

**Symptom::** NEW  
OR W  
ORSE  
NED  
MUS  
CLE P  
AIN

**Were fever o NO  
r systemic sy  
mptoms pre  
sent on the l  
ast day the S  
ubject Diary  
was complet  
ed?:**

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**2.g Symptom:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NEW OR WORSE NED JOIN T PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED JOIN T PAIN	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

			Were fever or NO r systemic sy mptoms pres ent on the la st day the Su bject Diary was complet ed?:	
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**2.h Symptom:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NEW OR WORSEN ED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
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**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE D NE SS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
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**Form Version:** 30-Jul-2020 21:30

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Injection Site R SW</b> <b>eaction::</b> EL LI NG	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

			<b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	
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**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29	ACV0PFEINFP6000	Emily Pierce	<b>Data Entry:</b> Injection Site PAI	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional Health Rochester General Hospital

Subject No: 10031186

Subject Initials: ---

Generated By: pfe.levissc

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.epierce)	<b>Reaction:</b> N AT INJE CTI ON SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 09:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> Sep/3/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> 97.9 <b>Temperature Unit:</b> <b>Temperature Location::</b> HEAD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

& Canada)

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> 97.9	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-03-2020 09:20:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-03-2020 09:21:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-03-2020 09:21:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-03-2020 15:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 09:21:03	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 09:21:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<b>Data Entry:</b> YES Date of Collection:  Sep/3/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-03-2020 15:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BP57L <b>D:</b> R	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-03-2020 15:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BP57LR	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-03-2020 10:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:05 (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
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Sep-03-2020 10:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Sep/3/2020 09:47	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-03-2020 10:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 10:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-07-2020 09:23:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b> F E V E R  Were fever or s N ystemic sympto O ms present on t he last day the Subject Diary was completed? :	Initial Entry

**2.a Symptom:**

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b> FA TI G U E	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Oct-07-2020	ACV0PFEINFP6000	Marie Francis	<b>Data Entry:</b>	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003 Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031186 Subject Initials: ---

Generated By: pfe.levissc Generated Time (GMT): 29-Mar-2021 04:04

09:24:06 (UTC-05:00) Eastern Time (US & Canada)		(pfe.mfrancis)	<b>Symptom::</b> HE A D AC HE  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	
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**2.c Symptom:**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

*2.d*

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> C HI L S N O</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b></p> <p>:</p>	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

**2.d Symptom:**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TI NG	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

			Were fever or NO systemic symptoms present on the last day the Subject Diary was completed?:	
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**2.e Symptom:**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Oct-07-2020	ACV0PFEINFP6000	Marie Francis	<b>Data Entry:</b>	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003 Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031186 Subject Initials: ---

Generated By: pfe.levissc Generated Time (GMT): 29-Mar-2021 04:04

09:24:06 (UTC-05:00) Eastern Time (US & Canada)		(pfe.mfrancis)	<b>Symptom::</b> DI A RR HE A  <b>Were fever or s N</b> <b>ystemic sympt O</b> <b>oms present on</b> <b>the last day the</b> <b>Subject Diary</b> <b>was completed</b> <b>?:</b>	
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**2.f Symptom:**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

2.g

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED MUS CLE P AIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

**2.g Symptom:**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NEW OR WORSE ED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR W ORSE NED JOIN T PAI N	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NEW OR WORSENED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levisssc **Generated Time (GMT):** 29-Mar-2021 04:04

Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry
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**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Injection Site</b> RE <b>Reaction::</b> D N ES S <b>Were injection</b> N <b>site reactions p</b> O <b>resent on the la</b> <b>st day the Subj</b> <b>ect Diary was c</b> <b>ompleted?:</b>	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Injection Site</b> SW <b>Reaction::</b> EL LI NG	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> Injection Site PAI	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)			<b>Reaction::</b> N A T IN JEC TIO N SI TE  <b>Were injectio</b> NO <b>n site reactio</b> <b>ns present on</b> <b>the last day t</b> <b>he Subject Di</b> <b>ary was com</b> <b>pleted?:</b>	
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**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> PAIN AT INJECTIO N SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 09:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-07-2020 09:24:15 (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-07-2020 09:24:15 (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-07-2020 10:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-07-2020 09:27:43	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031186**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 09:24:15 (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-07-2020 09:24:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> YES Date of Collection :  Oct/7/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 11:02:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> low draw	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

**5.a**

Date	Location	User	Value	Reason
Oct-07-2020 10:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BPYL9 <b>D:</b> N	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-07-2020 10:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BPYL9N	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-07-2020 10:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BNWKJ <b>D:</b> W	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

**5.b Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-07-2020 10:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BNWKJW	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-18-2020 16:14:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 4: Cl osed	Response satisfies query
Dec-18-2020 07:18:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Query 4: A nswered	Changed data per query
Dec-18-2020 06:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 4: O pened	DM: Kindly consider to update missing HEALTHCARE, ILL POTEN forms or else clarify. Thank you.
Dec-16-2020 00:00:46 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 3: Cl osed	Response satisfies query

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

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

Canada)				
Dec-15-2020 11:03:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Query 3: A nswered	Changed data per query
Dec-15-2020 03:58:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Bembem Takhellambam (pfe.takheb)	Query 3: O pened	DM: Date of Visit is completed but Nasal Swab (SWAB PFE) CRF is not initiated. Please review and update the data as appropriate. Thanks
Dec-14-2020 10:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: D eleted	Close Auto Query
Dec-14-2020 10:58:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: D eleted	Close Auto Query

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1003**Subject No:** 10031186**Generated By:** pfe.levisse**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Dec-14-2020 10:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: C andidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-14-2020 10:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: C andidate	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.
Dec-14-2020 10:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry</b> : Dec/14/202 0	Initial Entry

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

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

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

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

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

**Subject Initials:** ---

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

Dec-14-2020 10:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

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

**Form Status:** Data Complete

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

**Subject Initials:** ---

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> Dec/14/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> Dec/12/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Dec-29-2020 09:47:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> NO Date of Last Symptom R esolved:  Dec/24/20 20	New Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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

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

**Form Status:** Data Complete

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> YES	Initial Entry
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**4.a**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> Symptoms: FER Symptom Present:	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1003

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

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00)  
Eastern Time  
(US & Canada)

**4.b**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> <b>Symptom</b> NEW O R INCR s: EASED COUGH  <b>Symptom</b> YES <b>Present:</b>	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**4.b Symptoms:**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> NEW OR INC REASED COU GH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> YES	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> Sy NEW OR mpt INCREA oms SED SH : ORTNES S OF BR EATH	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

			Sy NO mpt om Pres ent:	
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**4.c Symptoms:**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> NEW OR INC REASED SHO RTNESS OF B REATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> Sympto CHI ms: LLS	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

(US & Canada)			<b>Symptom Present:</b> YES	
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**4.d Symptoms:**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> YES	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> Symptom: NEW OR R INCREASED MUSCLE PAIN	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
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**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Symptom Present:</b>	
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**4.e Symptoms:**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> YES	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> Symptom Loss: TASTE	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
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**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

(US & Canada)			OR SM ELL Sym YES ptom Present :	
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**4.f Symptoms:**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SM ELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> YES	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> Sym NEW O	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)			<b>pto R INCR</b> <b>ms: EASED</b> <b>SORE T</b> <b>HROAT</b>  <b>Sym YES</b> <b>pto</b> <b>m P</b> <b>rese</b> <b>nt:</b>	
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**4.g Symptoms:**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> NEW OR INC REASED SOR E THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> YES	Initial Entry

**4.h**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> <b>Sympto</b> DIA <b>ms:</b> RRH EA <b>Sympto</b> NO <b>m Prese</b> <b>nt:</b>	Initial Entry
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**4.h Symptoms:**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> <b>Sympto</b> VOM	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
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**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)			<b>ms:</b> ITIN G <b>Symptom Present:</b> NO	
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**4.i Symptoms:**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Dec-14-2020 10:58:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health  
Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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Date	Location	User	Value	Reason
Dec-15-2020 12:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Form Created	

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-15-2020 12:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> Dec/14/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-15-2020 12:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> SWABBED M ATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Dec-15-2020 12:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> NASOPHARY NX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Dec-15-2020 12:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	Initial Entry
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**5. Device Type:**

Date	Location	User	Value	Reason
Dec-15-2020 12:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Dec-15-2020 14:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> ROCHE MO LECULAR S YSTEMS CO BAS SARS- COV-2	Transcription Error
Dec-15-2020 12:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> CEPHEID X PERT XPRE SS SARS-CO V-2 TEST	Initial Entry

**7. Test Result:**

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levisse

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Dec-15-2020 12:41:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> POSITIVE	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-14-2020 10:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-14-2020 10:59:08 (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
Dec-14-2020 11:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-14-2020 10:59:08	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Can didate	'Sample Collected?' is

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1003**Subject No:** 10031186**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-14-2020 10:59:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> YES Date of Coll ection:  Dec/14/20 20	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-14-2020 11:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> CV2950 <b>D:</b> 3	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-14-2020 11:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> CV29503	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-15-2020 10:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-15-2020 10:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-15-2020 10:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Clos ed	Close Auto Query
Dec-15-2020 10:59:26	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ope ned	'Sample Collected?' is

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1003**Subject No:** 10031186**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Dec-15-2020 10:59:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<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
Dec-15-2020 10:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> subject completed self-swab	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020**Form Version:** 10-Dec-2020 02:26**Site No:** 1003**Subject No:** 10031186**Generated By:** pfe.levissc**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History**Form Status:** Data Complete**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> <b>Type of</b> SPE <b>Practitio</b> CIA <b>ner:</b> LIS T <b>Occure</b> NO <b>nce of Vi</b> <b>sits or C</b> <b>ontacts:</b>	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Eastern Time  
(US & Canada)

**1.b**

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> <b>Type of EME</b> <b>Practitioner:</b> RGE NCY ROO M <b>Occurrence of</b> <b>Visits or</b> <b>Contacts:</b> NO	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> Type o PRIM f Pract ARY itioner CARE : PHYS ICIAN	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Occurrence of Visits or Contacts:</b>	
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***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> Type of UR Practitioner GEN	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Eastern Time (US & Canada)			<b>ner:</b> T C ARE <b>Occurre</b> NO <b>nce of Vi</b> <b>sits or C</b> <b>ontacts:</b>	
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> URGENT CAR E	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> Type o TELE f Pract PHON	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Eastern Time (US & Canada)			<b>itioner E CO</b> <b>:</b> NSUL TATIO N <b>Occur NO</b> <b>rence</b> <b>of Visi</b> <b>ts or C</b> <b>ontact</b> <b>s:</b>	
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*I.e Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> TELEPHONE CONSULTATI ON	Initial Entry

*I.e Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NO	Initial Entry

*I.f*

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> <b>Type of P</b> OT <b>ractitione</b> HE <b>r:</b> R <b>Occurren</b> N <b>ce of Visit</b> O <b>s or Cont</b> <b>acts:</b>	Initial Entry
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***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	<b>Data Entry:</b> NO	Initial Entry

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Status:** Data Complete

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

Dec-18-2020 07:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> NO	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail  
History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail  
History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-18-2020 07:18:33 (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
Dec-18-2020 07:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> YES <i>Respiratory Ill ness Diagnosi s:</i>  COVID-19  Date of Diagn osis:  Dec/14/2020	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Dec-18-2020 07:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	<b>Data Entry:</b> 3	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit  
Trail History

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Jan-15-2021 09:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.a Test:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

& Canada)

**5.a LNMT**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.b LNMT**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levisse

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b>	Not Applicable	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Not Done:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.c LNMT**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b>	Not Applicable	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Not Done:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.d LNMT**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b>	Not Applicable	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.e LNMT**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levisse

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b>	Not Applicable	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Not Done:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.f LNMT**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levisse

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b>	Not Applicable	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

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**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
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**Subject No:** 10031186

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**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Jan-15-2021 09:43:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

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**Form Version:** 30-Jul-2020 21:27

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
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**4. Specimen Type:**

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**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
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**5.a Test:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

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**5.a Not Done:**

Date	Location	User	Value	Reason
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**Subject No:** 10031186

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**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

& Canada)

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Date	Location	User	Value	Reason
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**5.b**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

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**5.b Sponsor ID:**

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Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

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Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

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**5.b Not Done:**

Date	Location	User	Value	Reason
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**5.b LNMT**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

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**Site Name:** (1003) Rochester Regional HealthRochester  
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**5.c Sponsor ID:**

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**5.d**

Date	Location	User	Value	Reason
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**5.e**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

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**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Not Done:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.f LNMT**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form Version:** 30-Jul-2020 21:28

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b>	Not Applicable	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
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**Subject No:** 10031186

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**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

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Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

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**5.g Not Done:**

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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

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Hematology - eCRF Audit Trail History

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**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
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**Subject No:** 10031186

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**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.g LNMT**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levisse

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b>	Not Applicable	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

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**5.h Sponsor ID:**

Date	Location	User	Value	Reason
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Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.h LNMT**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b>	Not Applicable	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Result:**

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**5.i Not Done:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

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**Visit:** POT\_COVID\_ILL 1 -  
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Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
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Date	Location	User	Value	Reason
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**5.j**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

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**Form Version:** 30-Jul-2020 21:28

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**Generated By:** pfe.levissc

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Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Lab Normal Range:</b>	Not Applicable	
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**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

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**Form Version:** 30-Jul-2020 21:28

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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

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**Visit:** POT\_COVID\_ILL 1 -  
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**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
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**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

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Jan-15-2021 09:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.j LNMT**

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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Date:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Applicable <b>Systolic::</b> Not Applicable <b>Diastolic::</b> Not Applicable <b>Respiratory Rate in respirations/minute:</b> Not Applicable	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

			<b>Heart Rate i n beats/minu te:</b>	<b>Not Appli cable</b>
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**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Date:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> <b>Record Id</b> Not Ap <b>entifier::</b> plicable <b>Oxygen S</b> Not Ap <b>aturation:</b> plicable	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a SPO2 Pulse Oximetry %**

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1003

**Subject No:** 10031186

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**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Jan-15-2021 09:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** OXYGENATION PARAMETERS - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Jan-15-2021 09:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-15-2021 09:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Jan-15-2021 09:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Jan-15-2021 09:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

<b>4. Medication:</b>				
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Jan-15-2021 09:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Jan-15-2021 09:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Jan-15-2021 09:45:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** IMAGING - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-15-2021 09:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Jan-15-2021 09:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Jan-15-2021 09:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assessment:**

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/14/2020

**Form:** IMAGING - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Jan-15-2021 09:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/15/2021

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-15-2021 09:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/15/2021	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Jan-15-2021 09:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> COVID_A1	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/15/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-15-2021 09:42:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-15-2021 09:42:46 (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
Jan-15-2021 12:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-15-2021 09:42:46	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/15/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-15-2021 09:42:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES Date of Collection :  Jan/15/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-15-2021 12:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BPYLJ <b>D:</b> V	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-15-2021 12:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BPYLJV	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/15/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.b**

Date	Location	User	Value	Reason
Jan-15-2021 12:44:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I BNWK</b> <b>D: VG</b>	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-15-2021 12:44:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BNWKVG	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-15-2021 12:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I BNWK</b> <b>D: VH</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/15/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.c Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-15-2021 12:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BNWKVH	Initial Entry

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-07-2020 14:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-07-2020 14:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-07-2020 14:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1003) Rochester Regional Health  
Rochester General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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Date	Location	User	Value	Reason
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	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

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Category:**

Date	Location	User	Value	Reason
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-02-2021 12:31:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Mar-02-2021 12:31:49	ACV0PFEINFP6000	Kathryn Sewell	Query 3: Closed	Response satisfies query

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)		(pfe.sewelk02)		
Mar-02-2021 12:31:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Feb-26-2021 12:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 4: Answered	follow up SAE will be faxed today - contacted subject about barrier and subject acknowledged
Feb-26-2021 12:29:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 2: Answered	A follow - up SAE will be faxed today - partner age 32
Feb-26-2021 12:28:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 3: Answered	This is already stated on initial SAE and all Follow up forms
Feb-25-2021 10:24:37 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical - please submit a PG safety update with the

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

(US & Canada)				instructions given to subject 10031186 while his partner is pregnancy (ie, is a barrier method being used, etc)
Feb-25-2021 10:22:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical - please submit a PG safety update with the dates of subject 10031186 VAX3 and VAX4
Feb-25-2021 10:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued :Opened	Clinical - thank you for everything; please submit a PG safety update with female partner's age
Feb-24-2021 07:54:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 2: Answered	added and faxed yesterday 23-Feb
Feb-17-2021	ACV0PFEINFP6000	Kathryn	Query 2: Reissued	Clinical Please

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

02:33:02 (UTC-05:00) Eastern Time (US & Canada)		Sewell (pfe.sewelk02)	:Opened	submit study subject social information (smoke/drink /drugs) and submit female partner info if available (age, OB history, meds, social info, med conditions)
Feb-17-2021 02:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-16-2021 11:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	Submitted 15Feb2021
Feb-15-2021 22:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued :Opened	Clinical - Thank you; please submit this updated event term to the PG Safety report
Feb-15-2021 10:38:30	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				
Feb-15-2021 10:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-15-2021 10:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Exposure During partner Pregnancy	Transcription Error
Feb-15-2021 09:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Please submit study subject social information (smoke/drink /drugs) and submit female partner info if available (age, OB history, meds, social info, med conditions)
Feb-15-2021 09:30:46 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical As the subject is not the pregnancy person, EDP

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

(US & Canada)				term should be updated to 'Exposure during Partner Pregnancy' in both AE and PG safety report (#2021145233)
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Exposure During Pregnancy	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-17-2021 08:37:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Closed	Response satisfies query
Feb-16-2021 11:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	submitted 15Feb2021
Feb-15-2021 22:11:04 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	start date of 17Sep20 entered

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

(US & Canada)				
Feb-15-2021 22:10:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued :Opened	Clinical Thank you; please submit the start date to PG safety report (2021145233).
Feb-15-2021 11:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Feb-15-2021 11:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-15-2021 11:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Sep/17/2020 UNK :UNK	Initial Entry
Feb-15-2021 09:33:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Event Start date is missing; however, PG safety report has event start date of ?? 2000. Please update

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

				both locations with month and year (2000) if possible.
Feb-12-2021 07:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "Start Date" is missing. Kindly review and update.

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-15-2021 09:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Feb-15-2021 07:13:13 (UTC-05:00)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	Changed data per query

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Eastern Time (US & Canada)				
Feb-15-2021 07:11:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-12-2021 07:50:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "Toxicity Grade" is missing. Kindly review and update.

**7. Is the adverse event serious?**

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

***Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).***

Date	Location	User	Value	Reason
Feb-25-2021 10:18:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-24-2021 07:54:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 3: Answered	added and faxed yesterday 23-Feb
Feb-23-2021 15:54:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued :Opened	Clinical On the 2-page Exposure during PG form, relevant history & social habits (mother page 1/father page 2)
Feb-18-2021 02:48:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 2: Closed	Response satisfies query
Feb-17-2021 11:59:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Feb-17-2021 11:59:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-17-2021 11:59:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Changed Information
Feb-17-2021 02:36:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued :Opened	Clinical On the 2-page Exposure during PG form, relevant history & social habits (mother page 1/father page 2)
Feb-16-2021 11:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 3: Answered	please clarify where these are entered into EDC
Feb-16-2021 03:42:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Deleted	Query can be addressed internally
Feb-15-2021 22:02:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued :Opened	Clinical Father and Mother health characteristics as well as medications and social

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**Visit:** Logs - Unscheduled

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**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

				habits (smoke/drink) are standard reports for Exposure during Pregnancy safety events.
Feb-15-2021 21:59:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued :Opened	CLINICAL Thank you; however the event is still reported as a Serious event. AS per CRF completion guidelines, a pregnancy is NOT a serious event and no serious criteria are reported (unless an adverse outcome of pregnancy occurs like miscarriage)
Feb-15-2021 15:28:45 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 3: Answered	obesity is not clinically relevant to PG safety

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

(US & Canada)				
Feb-15-2021 11:20:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 2: Answered	Changed data per query

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1003

Site Name: (1003) Rochester Regional Health Rochester General Hospital

Subject No: 10031186

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:04

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**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Feb-15-2021 10:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Exposure During partner Pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-15-2021 09:47:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL For pertinent Med Hx (subject) please consider Obesity (BMI 42.7); if clinically relevant to PG safety event (#2021145233) please update Med Hx section
Feb-15-2021 09:32:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued: Opened	CLINICAL As per CRF CG 8.50.2.5, a healthy pregnancy is not an AE term; instead "Exposure During Partner Pregnancy" will be recorded as an AE in the CRF until 6 months after the last dose of study intervention

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**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-15-2021 07:15:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 2: An swere d	reported as serious and "important serious event"
Feb-15-2021 06:00:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 2: Op ened	SAE RECON: AER#2021145233,'EXPOSURE DURING PREGNANCY' event was appropriately reported to safety; however, seriousness criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.
Feb-15-2021 05:59:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Del eted	Query can be addressed internally
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ca ndidat e	For AE Exposure During Pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-10-2021 13:46:43	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry</b>	Initial Entry

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**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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(UTC-05:00)  
Eastern  
Time (US &  
Canada)

Is this serious event associated with congenital anomaly or birth defect?

NO

Did this serious event result in death?

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**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

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N	O	Did this serious event require or prolong hospitalization?
N	O	Did this serious event result in persistent or si

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**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

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			gnifi cant disa bilit y/in capa city ?  N O  Is th is se riou s ev ent l ife t hrea teni ng?  N O  Oth er m edic ally imp orta nt se riou	
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

			sevent	
			Y	
			ES	

**8. Is this adverse event the result of a study Medication Error?**  
**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  Partner became Pregnant	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-15-2021 21:57:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Clinical No current End date; no conflict with Unknown outcome.
Feb-15-2021 11:18:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 3: Answered	yes AE ongoing - baby not born so outcome is unknown. Following CRF instructions 8.5.3
Feb-15-2021 10:38:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Exposure During partner Pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

				still ongoing?" is marked "Yes".
Feb-15-2021 09:16:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Feb-15-2021 09:08:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 2: Closed	Response satisfies query
Feb-15-2021 07:08:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 2: Answered	Changed data per query
Feb-15-2021 07:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Exposure During Pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown'

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

				but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Feb-15-2021 07:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-15-2021 07:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> UNKNOWN	Initial Entry
Feb-12-2021 07:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM: The response for "What was the outcome of this adverse event?" is missing. Kindly review and update.

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-10-2021 13:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003 **Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186 **Subject Initials:** ---

**Generated By:** pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-19-2021 10:03:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/8/2021	Transcription Error
Jan-19-2021 10:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/19/2021	Initial Entry

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**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, Frozen, Verified

**Site No:** 1003      **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186      **Subject Initials:** ---

**Generated By:** pfe.levissc      **Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Jan-19-2021 10:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Participant is willing to return for Vaccinat ion 3 Participant is:  eligible per local/ national recomme ndations and conf irmed to have rec eived only placeb o at Vaccination 1 /2	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-15-2021 11:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/8/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-15-2021 11:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-22-2021 02:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Minal Pathak (pfe.patham13)	Query 1: Closed	Response satisfies query
Jan-21-2021 11:20:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	Changed data per query
Jan-21-2021 05:12:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Please consider updating INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION form as Not Applicable by selecting form level comment. Thank you.
Jan-19-2021 10:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/19/2021	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER  
VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Consent Was:*

Date	Location	User	Value	Reason
Jan-19-2021 10:37:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcridle)	<b>Data Entry:</b> OBTAINED Date Written Conse nt Obtained  Jan/19/2021	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-19-2021 10:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/19/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-19-2021 10:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-19-2021 10:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-19-2021 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-19-2021 10:38:31 (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
Jan-19-2021 15:03:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 10:38:31	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES Date of Collection :  Jan/19/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-19-2021 15:03:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BPYLK <b>D:</b> 2	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 15:03:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BPYLK2	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.b**

Date	Location	User	Value	Reason
Jan-19-2021 15:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I BNWK</b> <b>D: VR</b>	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 15:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BNWKVR	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-19-2021 15:03:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I BNWK</b> <b>D: VS</b>	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

**5.c Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-19-2021 15:03:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BNWKVS	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-19-2021 10:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-19-2021 10:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-19-2021 15:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 10:38:48	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 10:38:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES Date of Collection :  Jan/19/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-19-2021 15:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BPYLJ <b>D:</b> Z	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 15:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BPYLJZ	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-19-2021 10:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-19-2021 10:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-19-2021 10:44:33 (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
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-19-2021 10:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Jan/19/2021 10:38	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-19-2021 10:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-19-2021 10:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-19-2021 10:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-19-2021 10:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-19-2021 10:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-19-2021 10:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

Jan-19-2021 10:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry
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**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-15-2021 16:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Feb/9/2021	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-09-2021 15:36:16 (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
Feb-09-2021 15:36:16 (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
Feb-09-2021 15:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-09-2021 15:36:16	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional Health Rochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 15:36:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> YES Date of Collectio n:  Feb/9/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-09-2021 15:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> <b>Sample I</b> BPYLM <b>D:</b> R	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-09-2021 15:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	<b>Data Entry:</b> BPYLMR	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-15-2021 16:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-15-2021 16:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-15-2021 16:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.levisse

**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-15-2021 16:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Feb/9/2021 09:05	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-15-2021 16:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-15-2021 16:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Feb-15-2021 16:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-15-2021 16:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-15-2021 16:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-15-2021 16:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

Feb-15-2021 16:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry
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090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-12-2021 08:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Mar/11/2021	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Contact Type:**

Date	Location	User	Value	Reason
Mar-12-2021 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Mar-12-2021 08:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES Date of Contact:  Mar/11/2021	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:**  
FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit  
Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-12-2021 08:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Mar/11/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-12-2021 08:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREAT MENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-12-2021 08:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-07-2020 14:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-12-2020 10:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-12-2020 10:08:16 (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
Oct-07-2020 14:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/7/2020	Initial Entry
Aug-12-2020	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1003

**Site Name:** (1003) Rochester Regional HealthRochester General Hospital

**Subject No:** 10031186

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**Generated Time (GMT):** 29-Mar-2021 04:04

10:14:17 (UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Aug/12/2020	
Aug-12-2020 10:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/12/2020	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1003

**Subject No:** 10031186

**Generated By:** pfe.levissc

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1003) Rochester Regional HealthRochester  
General Hospital

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:04

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Sep-11-2020 14:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Edward Walsh (pfe.ewalsh)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae3d75\Final\Final On: 01-Apr-2021 04:34 (GMT)