

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** COHORT\_SELECTION

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

1.	Select appropriate response - Protocol version	30 JUN 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** MAIN INFORMED CONSENT

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

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

**Subject Initials:** ---

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

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**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jul/30/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** DEMOGRAPHY

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10031111]
2.	Birth Date:	(b) (6)/1994
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:	

<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031111	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levissc	

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

**eCRF Audit Trail History**

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

**Inclusion Criteria**

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

**Exclusion Criteria**

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00

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**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00

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**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01
2.k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.l	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2.m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

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**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**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	Jul/30/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]



**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**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:	[Migraines]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2007
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Jul/30/2020
2.	Weight:	[180.0]
3.	Unit:	LB
4.	Height:	[71.0]
5.	Unit:	in
6.	Body Mass Index:	[25.1]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	FOREHEAD

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<b>Header Text:</b> c4591001	<b>Form:</b> RANDOMIZATION
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031111	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levisse	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Jul/30/2020
2.	Randomization Number:	[40149]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BGJWD4]
5.b	Sample ID	[BGJWD5]
5.c	Sample ID	[BGJWD6]
5.d	Sample ID	[BNYFL6]
5.e	Sample ID	[BNYFL7]

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**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jul/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

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

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jul/30/2020 10:23
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**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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<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V2_VAX2_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031111	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levissc	

[eCRF Audit Trail History](#)

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



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - TEMP

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/20/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP57HN]
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**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** VACCINATION

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

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

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/20/2020 09:56
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

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

**Form:** 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:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

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**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Subject Initials:** ---

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

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYL77]
5.b	Sample ID	[BNWKD1]
5.c	Sample ID	[BNWKD2]

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

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

**Form Version:** 20-Feb-2021 02:17

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Signs and Symptoms**

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

**Symptoms**

4.	Symptoms:	
	Was symptom present?	

**Symptoms - Other**

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

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 20-Feb-2021 02:19

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Illness Details**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_CONVA - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/13/2020

**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:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/13/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/13/2020

**Form:** UNPLANNED VISIT

**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:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/13/2020

**Form:** CONTACT OUTCOME - UNPLANNED

**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:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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: Oct/13/2020  Contact Outcome: VISIT ARRANGED
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/13/2020

**Form:** VITAL SIGNS - TEMP

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

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

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/13/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	FOREHEAD

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/13/2020

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC  
EVENT

**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](#)

**Unplanned Assessment Of Local Reaction**

1.	Date of Assessment:	Oct/13/2020
2.	Injection Site Location	DELTOID MUSCLE
3.	Injection Site Body Side:	LEFT

**Reaction**

4.a	Reaction:	REDNESS
	Reaction Present:	NO
4.b	Reaction:	SWELLING
	Reaction Present:	NO

**Symptom**

5.a	Symptom:	PAIN AT INJECTION SITE
	Symptom Present:	NO
5.b	Symptom:	FATIGUE/TIREDNESS
	Symptom Present:	NO
5.c	Symptom:	HEADACHE
	Symptom Present:	NO
5.d	Symptom:	VOMITING
	Symptom Present:	NO
5.e	Symptom:	DIARRHEA
	Symptom Present:	NO
5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Symptom Present:	NO
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN
	Symptom Present:	NO
5.h	Symptom:	CHILLS
	Symptom Present:	NO

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**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:** 10031111

**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 :	Sep/23/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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



**Header Text:** c4591001

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

**Form:** DATE OF VISIT - REPEAT SWAB

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Date of Visit**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

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	psoriatic arthritis	Sep/26/2020 06:00	YES	<a href="#">Repeating Pages</a>

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

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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[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[psoriatic arthritis]	<a href="#">Comments</a>
4.	Start Date Time:	Sep/26/2020 06:00	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	2	
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? NO  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	RELATED	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	YES	
12.	Was a Non-Drug Treatment given?	NO	
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED	

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020501056]

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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>

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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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	[ ]

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1003

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

**Subject No:** 10031111

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

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

**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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**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:	//

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1003

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

**Subject No:** 10031111

**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	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**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?	

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Radiation Treatment**

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

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (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:** 10031111

**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>

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> Unplanned Vaccination - Unscheduled	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031111	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levissc	

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:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Vaccination**

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

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** CONTACT OUTCOME - MONTH 1

**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:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** CONTACT OUTCOME - MONTH 6

**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:** Potential ReVax Initial Contact - Unscheduled    **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:** 10031111    **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/29/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

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

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED

**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](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/29/2021
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:** 10031111

**Generated By:** pfe.levisse

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

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<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V101_VAX3	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031111	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levissc	

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** INFORMED CONSENT - FURTHER 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](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/2/2021
----	--------------	---

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** DISPOSITION - SCREENING FOR FURTHER 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](#)

**Disposition - Screening for Further Vaccination**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisc

**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: Feb/2/2021
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	[BPYLM9]
5.b	Sample ID	[BNWKXD]
5.c	Sample ID	[BNWKXF]

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

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

**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
3.	Sample Collected?	YES Date of Collection: Feb/2/2021
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	[BPYLM8]
-----	-----------	----------

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**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/2/2021 13:18
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

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<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V102_VAX4	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031111	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levissc	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Feb/22/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

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

**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
3.	Sample Collected?	YES Date of Collection: Feb/22/2021
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	[BPYLPS]
-----	-----------	----------

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**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/22/2021 13:29
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

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V103_MONTH1	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031111	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levissc	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Mar/2/2021
2.	Erroneous Visit	ERRONEOUS VISIT

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** CONTACT OUTCOME

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

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

**Subject Initials:** ---

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

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

**Contact Outcome**

1.	Contact Type:	Not Applicable _____	<a href="#">Comments</a>
2.	Was contact made?	Not Applicable _____	<a href="#">Comments</a>
3.	Comments:	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V104_MONTH6	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031111	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levissc	

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:** 10031111

**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:	[ ]

<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V105_MONTH18	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031111	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levissc	

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	



<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME
<b>Visit:</b> V105_MONTH18	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:04	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031111	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levisse	

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, Frozen, Verified

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Not Applicable _____ //	<a href="#">Comments</a>
2.	Phase of Disposition:	Not Applicable _____	<a href="#">Comments</a>
3.	Status:	Not Applicable _____	<a href="#">Comments</a>
4.	Specify Status:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

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

<b>Header Text:</b> c4591001	<b>Form:</b> CASEBOOK SIGNATURE FORM
<b>Visit:</b> Investigator Signature - Unscheduled	<b>Form Status:</b> Data Complete, Verified
<b>Form Version:</b> 22-Apr-2020 21:04	<b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital
<b>Site No:</b> 1003	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10031111	<b>Generated Time (GMT):</b> 29-Mar-2021 04:04
<b>Generated By:</b> pfe.levissc	

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
----	--------------------	--------------------------------------

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levissc

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

**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:** Logs - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - Comments

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Dec-24-2020 07:29:44 (UTC-05:00) Eastern Time (US & Canada)	Lauren Mitchell (pfe.lschneggenburger)	PI assessed this diagnosis as possibly related to IP - still being determined - future clinical assessments are scheduled

**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:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-03-2021 13:07:06 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** CONTACT OUTCOME - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-09-2021 13:08:05 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable



**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** CONTACT OUTCOME - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-09-2021 13:08:05 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** CONTACT OUTCOME - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Mar-09-2021 13:08:05 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** CONTACT OUTCOME - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Mar-09-2021 13:08:05 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

**Form:** DISPOSITION - TREATMENT - Comments

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

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

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-09-2021 07:55:56 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable
Form	Mar-09-2021 07:54:05 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
Form	Mar-09-2021 07:24:24 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** DISPOSITION - TREATMENT - Comments

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

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

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-09-2021 07:55:56 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable
1	Mar-09-2021 07:54:05 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
1	Mar-09-2021 07:24:24 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** DISPOSITION - TREATMENT - Comments

**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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Item	Date	User	Comment
2	Mar-09-2021 07:55:56 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable
2	Mar-09-2021 07:54:05 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
2	Mar-09-2021 07:24:24 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** DISPOSITION - TREATMENT - Comments

**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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Item	Date	User	Comment
3	Mar-09-2021 07:55:56 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable
3	Mar-09-2021 07:54:05 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
3	Mar-09-2021 07:24:24 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** DISPOSITION - TREATMENT - Comments

**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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Item	Date	User	Comment
4	Mar-09-2021 07:55:56 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable
4	Mar-09-2021 07:54:05 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
4	Mar-09-2021 07:24:24 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	Not Applicable



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

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

**Subject No:** 10031111

**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
Megan Helf	N/A	Feb-03-2021 13:02:34 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Edward Walsh	Approved	Jan-21-2021 22:05:59 (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.

Lauren Mitchell	N/A	Dec-08-2020 11:19:02 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Edward Walsh	Approved	Oct-20-2020 19:45:29 (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.

Megan Helf	N/A	Oct-13-2020 10:42:05 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**Affidavit:**

N/A

Edward Walsh	Approved	Sep-30-2020 15:47:33 (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	Sep-23-2020 12:22:44 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Edward Walsh	Approved	Aug-26-2020 11:34:13 (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.

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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levissc

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Jul-30-2020 11:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

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

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

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

**Subject Initials:** ---

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

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**I. Consent Was:**

Date	Location	User	Value	Reason
Jul-30-2020 11:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jul/30/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Jul-30-2020 11:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10031111	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Jul-30-2020 11:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1994	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Jul-30-2020 11:31:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Jul-30-2020 11:31:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR O F SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:31:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**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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*I. Date of Visit*

Date	Location	User	Value	Reason
Jul-30-2020 11:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jul/30/2020	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 17-Jul-2020 21:53**Site No:** 1003**Subject No:** 10031111**Generated By:** pfe.levisse**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criterion:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) <b>Criterion met?:</b> <b>Criterion ID:</b> IN01A00 <b>(For Pfizer use only):</b> :	Initial Entry

*I.a Inclusion Number:*

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 1	Initial Entry

*I.a Criterion Description:*

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

*I.a Criterion met?*

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

**I.a Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> IN01A00	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criterion Description:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures <b>Criterion met?:</b> <b>Criterion ID: (For Pfizer use only):</b> IN02A00	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

**I.b Inclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 2	Initial Entry

**I.b Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

**I.b Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

**I.b Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> IN02A00	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criterion Description:</b> Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator or to be eligible for inclusion in the study <b>Criterion met?:</b> YES	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			Criteria ID: (For Pfizer use only): IN03A00	
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**I.c Inclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 3	Initial Entry

**I.c Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

**I.c Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> IN03A00	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Inclusion Number:	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			<b>Criterion Description:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol  <b>Criterion met?:</b> YES  <b>Criterion ID: (For Pfizer use only):</b> IN04A00	
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**I.d Inclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 4	Initial Entry

**I.d Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

**I.d Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

**I.d Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> IN04A00	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38	ACV0PFEINFP6000	Megan	<b>Data Entry:</b>	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)		Helf (pfe.ahelf)	<b>Exclusion Number:</b> <b>Criterion Description:</b> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation <b>Criterion met?:</b> <b>Criterion ID:</b> EX01A00 <b>(For Pfizer use only):</b>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX01A00	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.b

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion 2</b> <b>Number:</b> <b>Criterion</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) <b>Criterion met?:</b> NO <b>Criterion EX02A00</b> <b>ID: (For Pfizer use only):</b>	Initial Entry

2.b Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX02A00	Initial Entry

2.c

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:53

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 3 <b>Exclusion Number:</b> <b>Criterion Description:</b> History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) <b>Criterion met?:</b> <b>Criterion ID: (For Pfizer use only):</b>	Initial Entry

2.c Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX03A00	Initial Entry

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Header Text: c4591001

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Form Version: 17-Jul-2020 21:53

Site No: 1003

Subject No: 10031111

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2.d

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion Description:</b> Receipt of medications intended to prevent COVID-19 <b>Criterion met?</b> NO <b>Criterion ID:</b> ( EX04A00 <b>For Pfizer use only):</b>	Initial Entry

2.d Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Megan Helf	<b>Data Entry:</b>	Initial Entry

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Site No: 1003

Subject No: 10031111

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(US & Canada)		(pfe.ahelf)	<b>Exclusion Number:</b> 8 <b>Criterion Description:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX08A00	
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**2.e Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 8	Initial Entry

**2.e Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

**2.e Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX08A00	Initial Entry

**2.f**

Date	Location	User	Value	Reason
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Form Version: 17-Jul-2020 21:53

Site No: 1003

Subject No: 10031111

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Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Exclusion Number: Criterion Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX10A00	Initial Entry
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2.f Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX10A00	Initial Entry

2.g

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Subject No: 10031111

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

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Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Number:</b> 11 <b>Criterion Description:</b> Women who are pregnant or breastfeeding <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX11A00	Initial Entry

**2.g Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 11	Initial Entry

**2.g Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Women who are pregnant or breastfeeding	Initial Entry

**2.g Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX11A00	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Number:</b> 12	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 12	Initial Entry

**2.h Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Previous vaccination with any coronavirus vaccine	Initial Entry

**2.h Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX12A00	Initial Entry

**2.i**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Number:</b> 13 <b>Criterion Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids <b>Criterion met?:</b> NO	Initial Entry

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Subject No: 10031111

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Subject Initials: ---

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			Criterion EX13A01 ID: (For Pfizer use only):	
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2.i Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Exclusion Number: Criterion Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study Criterion met?: NO	Initial Entry

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Subject Initials: ---

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			<b>Criterion ID: (For Pfizer use only):</b> EX14A01	
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**2.j Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 15	Initial Entry

**2.j Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

**2.j Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX14A01	Initial Entry

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Header Text: c4591001

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Subject No: 10031111

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2.k				
Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Number:</b> 16 <b>Criterion Description:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX15A01	Initial Entry

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Subject No: 10031111

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Subject Initials: ---

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2.k Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusion Number:</b> 17 <b>Criterion Description:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX16A01	Initial Entry

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Subject No: 10031111

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2.1 Exclusion Number:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Previous participation in other studies in volving study intervention containing lip id nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Exclusi 22</b> <b>on Nu</b> <b>mber:</b> <b>Criteria</b> Investigator site staff or Pfizer <b>on Des</b> employees directly involved in <b>criptio</b> the conduct of the study, site st <b>n:</b> aff otherwise supervised by the investigator, and their respecti ve family members <b>Criteria</b> NO <b>on met</b> <b>?:</b>	Initial Entry

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			<b>Criterion ID:</b> <b>(For Pfizer use only):</b>	
			EX21A01	

**2.m Exclusion Number:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 22	Initial Entry

**2.m Criterion Description:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

**2.m Criterion met?**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:34:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> EX21A01	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jul/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jul-30-2020 11:34:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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*I.a*

Date	Location	User	Value	Reason
Jul-30-2020 11:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Ter</b> Migraines <b>m:</b> <b>Start Date:</b> UNK/UNK/2005 <b>Ongoing:</b> NO End Date: UNK/UNK/2007	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Jul-30-2020 11:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Migraines	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Jul-30-2020 11:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Jul-30-2020 11:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO End Date: UNK/UNK/2007	Initial Entry

*I.b*

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jul-30-2020 11:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> Seasonal Allergies <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

***1.b Line/MH Number:***

Date	Location	User	Value	Reason
Jul-30-2020 11:37:38 (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
Jul-30-2020 11:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Seasonal Allergies	Initial Entry

***1.b Start Date:***

Date	Location	User	Value	Reason
Jul-30-2020 11:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Jul-30-2020 11:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jul/30/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 180.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 71.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 25.1	Initial Entry

**7.a**

Date	Location	User	Value	Reason
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090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Jul-30-2020 11:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.1 <b>Temperature Unit:</b> F <b>Temperature Location::</b> FOREHEAD	Initial Entry
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 98.1	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**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
Jul-30-2020 11:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jul/30/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Jul-31-2020 10:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> 40149	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:** 10031111**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jul-30-2020 11:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-30-2020 11:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-30-2020 11:36:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES Date of Collection:  Jul/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jul-30-2020 11:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BGJWD4	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jul-30-2020 11:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BGJWD4	Initial Entry



Header Text: c4591001  
 Visit: V1\_DAY1\_VAX1\_L  
 Form Version: 22-Apr-2020 21:03  
 Site No: 1003  
 Subject No: 10031111  
 Generated By: pfe.levisse

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

**5.b**

Date	Location	User	Value	Reason
Jul-30-2020 11:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BGJWD5	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jul-30-2020 11:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BGJWD5	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jul-30-2020 11:52:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BGJWD6	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jul-30-2020 11:52:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BGJWD6	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Jul-30-2020 11:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BNYFL6	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Jul-30-2020 11:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BNYFL6	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Jul-30-2020 11:52:15 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Madison Murphy	<b>Data Entry:</b> <b>Sample ID:</b> BNYFL7	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(US & Canada)		(pfe mmurphy)		
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**5.e Sample ID**

Date	Location	User	Value	Reason
Jul-30-2020 11:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BNYFL7	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Jul-30-2020 11:36:31 (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
Jul-30-2020 11:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jul-30-2020 11:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-30-2020 11:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-30-2020 11:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES Date of Collection:  Jul/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jul-30-2020 11:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> Sample ID: BGJWCZ	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jul-30-2020 11:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BGJWCZ	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jul-30-2020 11:35:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jul-30-2020 11:35:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jul-30-2020 11:35:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jul-30-2020 11:35:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jul/30/2020 10:23	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jul-30-2020 11:35:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jul-30-2020 11:35:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
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090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

Jul-30-2020 11:35:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jul-30-2020 11:35:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSER VATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jul-30-2020 11:35:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**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
Jul-30-2020 11:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES - REACTOGENICITY 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:** 10031111

**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-20-2020 11:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Symptom::</b> FAT IGU E <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<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
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Symptom::</b> HEA DAC HE <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Symptom::</b> CH ILL S	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Symptom::</b> VO MITI NG <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
			DIA RRH EA NO	

**2.f Symptom:**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
			NEW OR WORSENE D MUSCL E PAIN NO	

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:54**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031111**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**2.g Symptom:**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NEW OR WORSENERD 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
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENERD JOINT PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.lewissc

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

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RED NES S  <b>Were injection site reactions pre NO sent on the last day the Subject Diary was completed?:</b>	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLIN G  <b>Were injection site reactions pr NO esent on the last day the Subjec t Diary was completed?:</b>	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:46:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 30-Jul-2020 21:28

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.5 <b>Temperature Unit:</b> F <b>Temperature Location::</b> FOREHEAD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 97.5	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031111**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-20-2020 13:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-20-2020 11:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-20-2020 11:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES Date of Collection:  Aug/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-20-2020 13:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BP57HN	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-20-2020 13:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BP57HN	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Aug/20/2020 09:56	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
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090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

Aug-20-2020 11:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-20-2020 11:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSER VATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 11:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**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
Sep-23-2020 12:22:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:54**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031111**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b> FAT IGU E <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b> HEA DAC HE <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b> NO :	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b> CH ILL S	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b> VO MITI NG  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b> NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (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
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090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b>  DIA RRH EA  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
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2.f Symptom:

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b>  NEW OR WORSENE D MUSCL E PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:54**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031111**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04**2.g Symptom:**

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NEW OR WORSENE D MUSCLE PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENE D JOINT PAIN  <b>Were fever or systemic s</b> NO <b>ymptoms present on the</b> <b>last day the Subject Diar</b> <b>y was completed?:</b>	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.lewissc

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

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<u>Data Entry:</u> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<u>Data Entry:</u> Injection Site Reaction:: RED NESS S  Were injection site reactions pr NO esent on the last day the Subje ct Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLIN G  Were injection site reactions p NO resent on the last day the Subj ect Diary was completed?:	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (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
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<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-23-2020 12:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (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:** 10031111**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-23-2020 12:23:24 (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-23-2020 12:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-23-2020 14:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 12:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 12:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe mfrancis)	<b>Data Entry:</b> YES Date of Collection:  Sep/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-23-2020 14:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BPYL77	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-23-2020 14:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BPYL77	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:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.b**

Date	Location	User	Value	Reason
Sep-23-2020 14:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BNWKD1	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Sep-23-2020 14:23:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BNWKD1	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-23-2020 14:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BNWKD2	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Sep-23-2020 14:23:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BNWKD2	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/13/2020

**Form:** DATE OF VISIT - eCRF Audit Trail History

**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:** 10031111

**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-15-2020 05:34:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Deleted	No other assessments are performed at this visit.
Oct-14-2020 15:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-13-2020 10:42:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Feb-22-2021 15:59:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Changed Information
Oct-14-2020 15:13:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/13/2020**Form:** UNPLANNED VISIT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031111**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**I. Assessments**

Date	Location	User	Value	Reason
Feb-22-2021 23:44:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pramod Margaj (pfe margap03)	Query 4: Closed	Response satisfies query
Feb-22-2021 15:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 4: Answered	Changed data per query
Feb-22-2021 12:57:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cheryl Haseman (pfe hasemc)	Query 4: Opened	'Erroneous Visit' is marked in DOV CRF but data is present in this CRF. Please untick erroneous visit button in DOV CRF *if* visit occurred. Otherwise, add form-level comment = NOT APPLICABLE/NOT DONE to forms containing data within this visit.
Dec-08-2020 11:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Dec-08-2020 11:19:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Dec-08-2020 11:19:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry
Oct-14-2020 15:13:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-14-2020 15:13:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Changed Information
Oct-14-2020 15:13:13	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Contact Outcome is

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/13/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)				ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-13-2020 10:42:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 10:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Oct-13-2020 10:42:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Oct/13/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

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**1. Contact Type:**

Date	Location	User	Value	Reason
Dec-08-2020 11:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry
Oct-14-2020 15:13:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Oct-13-2020 10:42:28 (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
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Dec-08-2020 11:23:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-08-2020 11:23:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	<b>Data Entry:</b> YES Date of Contact:  Oct/13/2020  Contact Outcome:  VISIT ARRANGED	Transcription Error
Dec-08-2020 11:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Dec-08-2020 11:22:29	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Contact

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/13/2020**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031111**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				13/Nov/2020 is not equal to the Date of Visit 13/Oct/2020 within same unplanned visit. Please review and update as appropriate.
Dec-08-2020 11:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> YES Date of Contact:  Nov/13/2020  Contact Outcome:  VISIT ARRANGED	Initial Entry
Oct-14-2020 15:13:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Changed Information
Oct-14-2020 10:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Closed	Query to be raised post sanpshot
Oct-14-2020 04:57:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 1: Opened	PDQ : Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Oct-13-2020 10:42:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Oct-13-2020 10:42:28 (UTC-05:00) Eastern	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Oct/13/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)			Date of Contact: Oct/13/2020 Contact Outcome: VISIT ARRANGED	
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**3. Comments:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b>	Transcription Error
Dec-08-2020 11:22:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> Patient was seen in the office on 1 3NOV2020.	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/13/2020**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:01**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031111**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Feb-23-2021 07:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 1: Closed	Visit is not marked as Erroneous
Feb-22-2021 15:59:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	Changed data per query
Feb-22-2021 12:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cheryl Haseman (pfe.hasemc)	Query 1: Opened	'Erroneous Visit' is marked in DOV CRF but data is present in this CRF. Please untick erroneous visit button in DOV CRF *if* visit occurred. Otherwise, add form-level comment = NOT APPLICABLE/NOT DONE to forms containing data within this visit.
Dec-08-2020 11:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-08-2020 11:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.6 <b>Temperature Unit:</b> F <b>Temperature Locati</b> <b>on::</b> FOREHEA D	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-08-2020 11:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> 1	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/13/2020

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

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

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**2.a Temperature:**

Date	Location	User	Value	Reason
Dec-08-2020 11:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> 97.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Dec-08-2020 11:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Dec-08-2020 11:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> FOREHEAD	Initial Entry

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**Header Text:** c4591001**Visit:** Unplanned 1 - Unscheduled Visit on  
Oct/13/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1003**Subject No:** 10031111**Generated By:** pfe.levisse**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC  
EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-23-2021 09:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Feb-22-2021 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	Changed data per query
Feb-22-2021 12:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cheryl Haseman (pfe.hasemc)	Query 1: Opened	'Erroneous Visit' is marked in DOV CRF but data is present in this CRF. Please untick erroneous visit button in DOV CRF *if* visit occurred. Otherwise, add form-level comment = NOT APPLICABLE/NOT DONE to forms containing data within this visit.
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**2. Injection Site Location**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**3. Injection Site Body Side:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> LEFT	Initial Entry

**4.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
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**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC  
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**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-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> <b>Reaction::</b> REDNESS <b>Reaction Present::</b> NO	Initial Entry
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**4.a Reaction:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> REDNESS	Initial Entry

**4.a Reaction Present:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> <b>Reaction::</b> SWELLING <b>Reaction Present::</b> NO	Initial Entry

**4.b Reaction:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> SWELLING	Initial Entry

**4.b Reaction Present:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> <b>Symptom::</b> PAIN AT INJECTI ON SITE	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

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Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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

			Symptom Present:: NO	
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5.a Symptom:

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Data Entry: Symptom: FATIGUE/TIRE DNESS Symptom Present: NO	Initial Entry

5.b Symptom:

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Data Entry: FATIGUE/TIREDNESS	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Data Entry: Symptom: HEADACHE	Initial Entry

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Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

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			Symptom Present: NO :	
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5.c Symptom:

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> HEADACHE	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NO	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> <b>Symptom::</b> VOMITING <b>Symptom Present::</b> NO	Initial Entry

5.d Symptom:

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> VOMITING	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NO	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> <b>Symptom::</b> DIARRHEA <b>Symptom Present::</b> NO	Initial Entry

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**Header Text:** c4591001

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**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.lewissc

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC  
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**Form Status:** Data Complete, Frozen, Verified

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**5.e Symptom:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**5.e Symptom Present:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NO	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> Symptom: NEW OR WORSEN : ED MUSCLE PAIN Symptom NO Present::	Initial Entry

**5.f Symptom:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NEW OR WORSENED MUSCLE PAIN	Initial Entry

**5.f Symptom Present:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NO	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> Symptom:: NEW OR WORSEN ED JOINT PAIN Symptom NO Present::	Initial Entry

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**Generated By:** pfe.levisse

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC  
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**5.g Symptom:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NEW OR WORSENERD JOINT P AIN	Initial Entry

**5.g Symptom Present:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NO	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> <b>Symptom::</b> CHILLS <b>Symptom Present::</b> NO	Initial Entry

**5.h Symptom:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> CHILLS	Initial Entry

**5.h Symptom Present:**

Date	Location	User	Value	Reason
Dec-08-2020 11:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<b>Data Entry:</b> NO	Initial Entry

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**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:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Sep-24-2020 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-24-2020 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-24-2020 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<b>Data Entry:</b> COMPLETED	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Oct-14-2020 15:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Form Created	

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Subject No: 10031111

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Oct-14-2020 15:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-14-2020 15:23:47 (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
Feb-25-2021 15:26:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Closed	closing a query on a deleted AE
Feb-24-2021 14:29:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 5: Answered	start date faxed to safety
Feb-22-2021 20:12:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 5: Opened	CLINICAL - please submit a SAE safety update reporting the start date of leflunomide, if known
Jan-22-2021 22:48:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Jan-22-2021 13:55:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 4: Answered	psoriatic arthritis remained the diagnosis on the rheumatology follow up.
Jan-21-2021 00:04:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	CLINICAL Event term is Psoriatic Arthritis; however, SAE report states that Rheumatologist considered both Reactive Arthritis & PSA. Please confirm

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<b>Header Text:</b> c4591001 <b>Visit:</b> Logs - Unscheduled <b>Form Version:</b> 22-Apr-2020 21:02 <b>Site No:</b> 1003 <b>Subject No:</b> 10031111 <b>Generated By:</b> pfe.levisse				
<b>Form:</b> ADVERSE EVENT REPORT - eCRF Audit Trail History <b>Form Status:</b> Data Complete, Verified <b>Site Name:</b> (1003) Rochester Regional HealthRochester General Hospital <b>Subject Initials:</b> --- <b>Generated Time (GMT):</b> 29-Mar-2021 04:04				
				PSA remained the diagnosis on Rheum followup
Jan-21-2021 00:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	rewording query
Jan-20-2021 23:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	CLINICAL Event term is Psoriatic Arthritis; however, SAE report states that Rheumatologist diagnosis was Reactive Arthritis. Please review event term, and update in AE/SAE if appropriate
Dec-24-2020 09:02:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	clin: Thank you. Can you address PI rationale for assessment as 'possibly related'
Dec-24-2020 07:30:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Query 1: Answered	Added a level comment to address "relatedness"
Dec-22-2020 22:15:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Dec-22-2020 13:23:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Reissued:Opened	clinical: Thank you. Pls address biological basis for assessment as 'related'
Dec-22-2020 11:37:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Query 1: Answered	No prior history known - this is a new diagnosis. Subject awaiting treatment.
Dec-21-2020 14:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Query 2: Answered	subject has had no iron studies
Dec-21-2020 11:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Thank you for the extensive SAE lab reporting section; please confirm if subject has had iron studies (young M with asymmetric small jt

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				arthritis).
Dec-21-2020 11:14:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clin: pls advise on biological basis for determination as 'related', confirm this is a new diagnosis and advise on what treatment subject has received. Confirm no prior hx of joint pains or psoriasis or update MedHx CRF accordingly Thanks
Dec-18-2020 12:30:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> psoriatic arthritis	New Information
Oct-14-2020 15:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Tenosynovitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-14-2020 15:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Sep/26/2020 06:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-14-2020 15:23:47 (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
Oct-14-2020 15:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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Date	Location	User	Value	Reason
Dec-22-2020 05:38:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 12:30:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE psoriatic arthritis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-18-2020 12:27:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Tenosynovitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-18-2020 12:27:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO  Did this serious event require or prolong hospitalization?  NO  Did this serious event result in persistent or significant disability/incapacity?  NO  Is this serious event life threatening?  NO  Other medically important serious event  YES	New Information

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Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Oct-14-2020 15:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry
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**8. Is this adverse event the result of a study Medication Error?**  
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-14-2020 15:23:47 (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
Dec-21-2020 11:30:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Dec-21-2020 10:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-21-2020 10:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> RELATED	New Information
Dec-18-2020 13:09:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Event Relationship to study treatment is NOT RELATED; however, SAE report has RELATED. Please review, harmonize reporting, and update in the appropriate location.
Oct-14-2020 15:23:47 (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  If Other, specify:  unknown	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
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090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Oct-14-2020 15:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-14-2020 15:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-14-2020 15:23:47 (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
Oct-14-2020 15:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 15:23:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Dec-22-2020 05:38:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quiton)	<b>Data Entry:</b> 2020501056	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled    **Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-03-2021 13:02:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jan/29/2021	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**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:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

**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
Feb-03-2021 13:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 13:02:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-03-2021 13:02:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per other protocol allowance (s) and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levissc

**Form:** TREATMENT UNBLINDED - 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 Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-03-2021 13:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Jan/29/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-03-2021 13:14:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIO NAL VACCINATION	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-03-2021 13:04:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Feb/2/2021	Initial Entry

**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:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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***I. Consent Was:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-03-2021 13:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Feb/2/2021	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF  
Audit Trail History

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

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

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-03-2021 13:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Feb/2/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-03-2021 13:05:27 (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
Feb-03-2021 13:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (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:** 10031111**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-03-2021 13:08:42 (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-03-2021 13:08:42 (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
Feb-03-2021 13:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 13:08:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-03-2021 13:08:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES Date of Collection:  Feb/2/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-03-2021 13:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BPYLM9	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-03-2021 13:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BPYLM9	Initial Entry

**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:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.b**

Date	Location	User	Value	Reason
Feb-03-2021 13:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BNWKXD	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-03-2021 13:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BNWKXD	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-03-2021 13:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BNWKXF	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-03-2021 13:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BNWKXF	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (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: 10031111

Subject Initials: ---

Generated By: pfe.levisse

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-03-2021 13:13:38 (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-03-2021 13:13:38 (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-03-2021 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 13:13:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-03-2021 13:13:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES Date of Collection:  Feb/2/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-03-2021 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> Sample ID: BPYLM8	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-03-2021 13:31:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BPYLM8	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

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-03-2021 13:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-03-2021 13:14:21 (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-03-2021 13:14:21 (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
Feb-03-2021 13:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Feb/2/2021 13:18	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-03-2021 13:14:21 (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-03-2021 13:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
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090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

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-03-2021 13:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-03-2021 13:14:21 (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-03-2021 13:14:21 (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-03-2021 13:14:21 (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
Feb-03-2021 13:14:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-03-2021 13:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Feb/22/2021	Initial Entry

**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:** 10031111**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-22-2021 16:57:35 (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-22-2021 16:57:35 (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-22-2021 16:57:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 16:57:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-22-2021 16:57:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> YES Date of Collection:  Feb/22/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-22-2021 16:57:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> <b>Sample ID:</b> BPYLPS	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-22-2021 16:57:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<b>Data Entry:</b> BPYLPS	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

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
Mar-03-2021 13:34:16 (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
Mar-03-2021 13:34:16 (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
Mar-03-2021 13:34:16 (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
Mar-03-2021 13:34:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Feb/22/2021 13:29	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Mar-03-2021 13:34:16 (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
Mar-03-2021 13:34:16 (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
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090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)



Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

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

Mar-03-2021 13:34:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**8. Actual Dose:**

Date	Location	User	Value	Reason
Mar-03-2021 13:34:16 (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
Mar-03-2021 13:34:16 (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
Mar-03-2021 13:34:16 (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
Mar-03-2021 13:34:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Mar-12-2021 09:51:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 6: Del eted	Query is invalid or does not apply
Mar-10-2021 04:42:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloim (pfe moloim)	Query 4: Clo sed	Response satisfies query
Mar-09-2021 13:18:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Can didate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-09-2021 13:15:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Del eted	Close Auto Query
Mar-09-2021 13:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Can didate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-09-2021 07:53:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Query 4: Ans wered	Changed data per query
Mar-09-2021 01:10:05 (UTC-05:00) Eastern Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 4: Op ened	DMW7636050;V103 Visit Date is entered, but Disposition - Treatment form at FURTHER_VACCINATION_EOT

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levisse

**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

(US & Canada)				visit is not completed. Please review and update as appropriate.
Mar-08-2021 08:09:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Clo sed	Close Auto Query
Mar-08-2021 01:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swapna Varikuti (pfe.variks)	Query 2: Clo sed	Erroneous Visit is marked
Mar-08-2021 00:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jayesh Yeole (pfe.yeolej)	Query 3: Op ened	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-05-2021 11:44:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 2: Ans wered	erroneous visit - did not occur yet
Mar-05-2021 08:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Can didate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Mar-05-2021 01:35:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Deepthi Chandrasekaran (pfe.chandd38)	Query 2: Op ened	PDQ: Date of visit V103_MONTH1 is out of window for -20 days from V102_VAX4 DOV or Vaccination date. Please verify and update. Else, confirm in query response appropriately.
Mar-04-2021 15:09:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katerina Trpeski (pfe.TRPEsk)	Query 1: Clo sed	Response satisfies query

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V103\_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

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

Mar-04-2021 07:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Ans wered	Changed data per query
Mar-04-2021 04:18:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Op ened	DM: Patient completed Vaccination 3 visit through the 1-month post vaccination visit after the Vaccination 4. Please complete treatment disposition CRF and update date of EOT2 to match date of visit at visit 103.
Mar-03-2021 13:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry</b> : Mar/2 /2021	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Mar-09-2021 13:18:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry
Mar-09-2021 13:15:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b>	Transcription Error
Mar-09-2021 13:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry
Mar-08-2021 08:09:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<b>Data Entry:</b>	Transcription Error
Mar-05-2021 08:34:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V103\_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031111

Generated By: pfe.levisse

Form: CONTACT OUTCOME - 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. Contact Type:**

Date	Location	User	Value	Reason
Mar-09-2021 13:08:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-09-2021 13:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Mar-03-2021 13:47:45 (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-09-2021 13:08:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-09-2021 13:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Changed Information
Mar-03-2021 13:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> YES Date of Contact:  Mar/2/2021	Initial Entry

**3. Comments:**

Date	Location	User	Value	Reason
Mar-09-2021 13:08:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (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, Frozen, Verified

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**I. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-09-2021 07:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Not Applicabl e	Initial Entry
Mar-09-2021 07:55:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Changed Information
Mar-09-2021 07:54:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Mar/2/2021	Initial Entry
Mar-09-2021 07:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Initial Entry
Mar-09-2021 07:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicabl e	Initial Entry
Mar-05-2021 08:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Changed Information
Mar-05-2021 03:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Close d	Auto closed by Validation Check: VC_DS001_21
Mar-04-2021 18:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Open ed	DMW7602001;Status on the Disposition - Treatment form is COMPLETED, but Date is different than

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (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, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031111

Subject Initials: ---

Generated By: pfe.lewissc

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

				Visit 3 Date. Please review and update as appropriate.
Mar-04-2021 07:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Mar/2/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-09-2021 07:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-09-2021 07:55:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Mar-09-2021 07:54:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry
Mar-09-2021 07:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry
Mar-09-2021 07:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-05-2021 08:34:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Mar-04-2021 07:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-09-2021 07:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-09-2021 07:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Changed Information

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (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, Frozen, Verified

**Site No:** 1003

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

**Subject No:** 10031111

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Mar-09-2021 07:54:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> COMPLETED	Initial Entry
Mar-09-2021 07:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Initial Entry
Mar-09-2021 07:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-05-2021 08:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Changed Information
Mar-04-2021 07:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> COMPLETED	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Mar-09-2021 07:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-09-2021 07:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<b>Data Entry:</b>	Initial Entry
Mar-09-2021 07:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

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**1. Subject Status**

Date	Location	User	Value	Reason
Sep-24-2020 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Jul-30-2020 11:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Jul-30-2020 11:34:47 (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
Dec-22-2020 05:40:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Dec-21-2020 14:19:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Query 1: Answered	Original value is correct
Dec-18-2020 09:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020501056 psoriatic arthritis) (26Sep2020) was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-24-2020 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/23/2020	Initial Entry
Jul-30-2020 11:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jul/30/2020	Initial Entry
Jul-30-2020 11:34:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jul/30/2020	Initial Entry

090177e196ae3d69\Final\Final On: 01-Apr-2021 04:33 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1003

**Subject No:** 10031111

**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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*I. Casebook Signature*

Date	Location	User	Value	Reason
Aug-26-2020 11:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Edward Walsh (pfe.ewalsh)	<b>Data Entry:</b> Click Here to Enable	Initial Entry