

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1003

Subject No: 10031197

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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/13/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031197

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	[10031197]
2.	Birth Date:	(b) (6)/1978
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/13/2020	Comments
2.	Erroneous Visit		Comments

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1003

Subject No: 10031197

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

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 _____
----	---	-------------------------

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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	Aug/13/2020
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: 10031197

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

Form Comments

Medical History Details

1.	Line/MH Number:	Not Applicable _____
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1003

Subject No: 10031197

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:	Aug/13/2020
2.	Weight:	[180.0]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[24.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001	Form: RANDOMIZATION
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:03	Site Name: (1003) Rochester Regional HealthRochester General Hospital
Site No: 1003	Subject Initials: ---
Subject No: 10031197	Generated Time (GMT): 29-Mar-2021 04:04
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Aug/13/2020
2.	Randomization Number:	[48777]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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: Aug/13/2020
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	[BP57CN]
5.b	Sample ID	[BP57CP]
5.c	Sample ID	[BP57CR]
5.d	Sample ID	[BKDZ52]
5.e	Sample ID	[BKDZ53]

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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/13/2020
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	[BP57D6]
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090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031197

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/13/2020 15:21
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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1003

Subject No: 10031197

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
----	---	---

Header Text: c4591001	Form: DATE OF VISIT
Visit: V2_VAX2_L	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1003) Rochester Regional HealthRochester General Hospital
Site No: 1003	Subject Initials: ---
Subject No: 10031197	Generated Time (GMT): 29-Mar-2021 04:04
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1003

Subject No: 10031197

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:	Sep/3/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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: Sep/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP57LM]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031197

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:	Sep/3/2020 11:43
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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/5/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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: Oct/5/2020
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	[BPYL9D]
5.b	Sample ID	[BNWKJB]
5.c	Sample ID	[BNWKJC]

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (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: 10031197

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: 10031197

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:	[]
----	------------------------	-----

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: 10031197

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: 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: 10031197

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: 10031197

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:	[]
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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: 10031197

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: 10031197

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:	
----	-------------------------	--

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: 10031197

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: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

Unplanned Assessments

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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1003

Subject No: 10031197

Generated By: pfe.levissc

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/5/2020
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: 10031197

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: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

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: 10031197

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. DELETED	ADVERSE EVENT	1	right ureteropelvic junction obstruction	Jan/13/2021 13:19	NO End Date Time: Jan/27/2021 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Congenital right ureteropelvic junction obstruction	Dec/1/2020 UNK:UNK	NO End Date Time: Jan/27/2021 UNK:UNK	Repeating Pages

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[right ureteropelvic junction obstruction]
4.	Start Date Time:	Jan/13/2021 13:19
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/27/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [ureteropelvic junction obstruction]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Congenital right ureteropelvic junction obstruction]
4.	Start Date Time:	Dec/1/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/27/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? YES Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [ureteropelvic junction obstruction]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021124061]

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: 10031197

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.						Repeating Pages

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031197

Generated By: pfe.levissc

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	[]

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (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: 10031197

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.	1	VACCINATIONS	NO	Quadrivalent Influenza Vaccine	Oct/UNK/2020	Repeating Pages

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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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[Form Audit Trail](#)

Concomitant Medications

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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (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: 10031197

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.						Repeating Pages

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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

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Concomitant Medications

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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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.						Repeating Pages

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

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?	

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: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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:	//

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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: 10031197

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?	

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001		Form: CONTACT OUTCOME - MONTH 1
Visit: Unplanned Vaccination - Unscheduled		Form Status: Not Started
Form Version: 10-Oct-2020 15:57		Site Name: (1003) Rochester Regional HealthRochester General Hospital
Site No: 1003		Subject Initials: ---
Subject No: 10031197		Generated Time (GMT): 29-Mar-2021 04:04
Generated By: pfe.levisse		
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: 10031197

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: 10031197

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/16/2020
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: 10031197

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 local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001	Form: DATE OF VISIT
Visit: V101_VAX3	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1003) Rochester Regional HealthRochester General Hospital
Site No: 1003	Subject Initials: ---
Subject No: 10031197	Generated Time (GMT): 29-Mar-2021 04:04
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Dec/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1003

Subject No: 10031197

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 Dec/17/2020
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1003

Subject No: 10031197

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: 10031197

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 :	Dec/17/2020
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: 10031197

Generated By: pfe.levisse

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: Dec/17/2020
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	[BPYLCZ]
5.b	Sample ID	[BNWKN1]
5.c	Sample ID	[BNWKN2]

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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: Dec/17/2020
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	[BPYLCS]
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090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1003

Subject No: 10031197

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:	Dec/17/2020 14:53
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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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 :	Dec/16/2020
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: 10031197

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: 10031197

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:	[]

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/6/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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: Jan/6/2021
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	[BPYLGs]
-----	-----------	----------

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1003

Subject No: 10031197

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:	Jan/6/2021 14:25
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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001	Form: DATE OF VISIT
Visit: V103_MONTH1	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1003) Rochester Regional HealthRochester General Hospital
Site No: 1003	Subject Initials: ---
Subject No: 10031197	Generated Time (GMT): 29-Mar-2021 04:04
Generated By: pfe.levissc	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Feb/5/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031197

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/5/2021
3.	Comments:	[]

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	Form: CONTACT OUTCOME
Visit: V104_MONTH6	Form Status: Not Started
Form Version: 22-Apr-2020 21:04	Site Name: (1003) Rochester Regional HealthRochester General Hospital
Site No: 1003	Subject Initials: ---
Subject No: 10031197	Generated Time (GMT): 29-Mar-2021 04:04
Generated By: pfe.levisse	

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	Form: CONTACT OUTCOME
Visit: V105_MONTH18	Form Status: Not Started
Form Version: 22-Apr-2020 21:04	Site Name: (1003) Rochester Regional HealthRochester General Hospital
Site No: 1003	Subject Initials: ---
Subject No: 10031197	Generated Time (GMT): 29-Mar-2021 04:04
Generated By: 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: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Feb/5/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisc

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	Oct/5/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031197

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levissc

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

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: DATE OF VISIT - Comments

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](#)

Item	Date	User	Comment
Form	Aug-13-2020 15:39:39 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
Form	Aug-13-2020 15:37:23 (UTC-05:00) Eastern Time (US & Canada)	Emily Pierce (pfe.epierce)	Not Applicable

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: DATE OF VISIT - Comments

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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Item	Date	User	Comment
1	Aug-13-2020 15:39:39 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
1	Aug-13-2020 15:37:23 (UTC-05:00) Eastern Time (US & Canada)	Emily Pierce (pfe.epierce)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: DATE OF VISIT - Comments

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](#)

Item	Date	User	Comment
2	Aug-13-2020 15:39:39 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	
2	Aug-13-2020 15:37:23 (UTC-05:00) Eastern Time (US & Canada)	Emily Pierce (pfe.epierce)	Not Applicable

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

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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Item	Date	User	Comment
Form	Aug-13-2020 15:39:53 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - Comments

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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Item	Date	User	Comment
Form	Aug-13-2020 15:41:54 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	no medical history to report <hr/> Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION -
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
Form	Dec-18-2020 07:52:04 (UTC-05:00) Eastern Time (US & Canada)	Lauren Mitchell (pfe.lschneggenburger)	all inclusion met/no exclusion met <hr/> 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: 10031197

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
Lauren Mitchell	N/A	Dec-17-2020 14:35:59 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Edward Walsh	Approved	Oct-12-2020 10:48:03 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

Affidavit:

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

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

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

Megan Helf	N/A	Oct-05-2020 11:33:56 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Edward Walsh	Approved	Sep-12-2020 11:21:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

Affidavit:

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

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

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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1003

Subject No: 10031197

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
Aug-13-2020 14:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 14:30:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

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
Aug-13-2020 14:30:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: OBTAINED Date Written Consent Obtained Aug/13/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031197

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
Aug-13-2020 14:30:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10031197	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-13-2020 14:30:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1978	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-13-2020 14:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-13-2020 14:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 14:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: WHITE	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

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-13-2020 15:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Aug/13/2020	Initial Entry
Aug-13-2020 15:39:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry:	Initial Entry
Aug-13-2020 15:37:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Not Applicable	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Aug-13-2020 15:39:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry:	Initial Entry
Aug-13-2020 15:37:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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
Aug-13-2020 15:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Aug/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-13-2020 15:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-13-2020 15:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1003

Subject No: 10031197

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
Aug-13-2020 15:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Aug/13/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-13-2020 15:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 180.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-13-2020 15:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-13-2020 15:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 72.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-13-2020 15:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-13-2020 15:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24.4	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1003

Subject No: 10031197

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

Aug-13-2020 15:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-13-2020 15:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-13-2020 15:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 97.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-13-2020 15:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-13-2020 15:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-13-2020 15:40:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Aug/13/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-13-2020 15:40:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 48777	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: 10031197
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
Aug-13-2020 15:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-13-2020 15:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-13-2020 15:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 15:40:26 (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-13-2020 15:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Collection: Aug/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-13-2020 15:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BP57CN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 15:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BP57CN	Initial Entry

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
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 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: ---
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5.b				
Date	Location	User	Value	Reason
Aug-13-2020 15:44:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BP57CP	Initial Entry

5.b Sample ID				
Date	Location	User	Value	Reason
Aug-13-2020 15:44:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BP57CP	Initial Entry

5.c				
Date	Location	User	Value	Reason
Aug-13-2020 15:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BP57CR	Initial Entry

5.c Sample ID				
Date	Location	User	Value	Reason
Aug-13-2020 15:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BP57CR	Initial Entry

5.d				
Date	Location	User	Value	Reason
Aug-13-2020 15:45:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BKDZ52	Initial Entry

5.d Sample ID				
Date	Location	User	Value	Reason
Aug-13-2020 15:45:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BKDZ52	Initial Entry

5.e				
Date	Location	User	Value	Reason
Aug-13-2020 15:45:07 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Madison Murphy	<u>Data Entry:</u>	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

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Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)		(pfe mmurphy)	Sample ID: BKDZ53	
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 15:45:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BKDZ53	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:** 10031197**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-13-2020 15:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-13-2020 15:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-13-2020 15:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 15:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-13-2020 15:40:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Collection: Aug/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-13-2020 15:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BP57D6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 15:47:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BP57D6	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031197

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-13-2020 16:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-13-2020 16:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-13-2020 16:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-13-2020 16:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Aug/13/2020 15:21	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-13-2020 16:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-13-2020 16:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031197

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-13-2020 16:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-13-2020 16:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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-13-2020 16:18:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1003

Subject No: 10031197

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
Aug-13-2020 15:40:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 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: 10031197

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
Sep-03-2020 13:00:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Sep/3/2020	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031197**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-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Symptom:: FE VE R Were fever or systemic symptom NO s present on the last day the Subj ect Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Symptom:: FAT IGU E Were fever or systemic sympto NO ms present on the last day the S ubject Diary was completed?:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> Symptom:: CH ILL S	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> Symptom:: VO MITI NG Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

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Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry
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2.f Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Symptom:: NEW OR WORSENE D MUSCL E PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> NEW OR WORSENER 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-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> Symptom:: NEW OR WORSENER ED JOINT PAIN Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> NEW OR WORSENER JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

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Subject Initials: ---

Generated By: pfe.levisse

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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> Injection Site Reaction:: RED NES S Were injection site reactions pr NO esent on the last day the Subjec t Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<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-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<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

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 13:01:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1003

Subject No: 10031197

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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I. Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Sep/3/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-03-2020 13:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Record Identifier:: 1 Temperature: 97.6 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 97.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 13:01:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031197**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-03-2020 13:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 13:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 15:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 13:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 13:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 15:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BP57LM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 15:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BP57LM	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1003**Subject No:** 10031197**Generated By:** pfe.levisse**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-03-2020 13:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 13:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-03-2020 13:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 13:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Sep/3/2020 11:43	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 13:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 13:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031197

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

Sep-03-2020 13:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-03-2020 13:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Sep-03-2020 13:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

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
Oct-05-2020 11:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Oct/5/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: FAT IGU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

2.b Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> <u>Symptom::</u> HEA DAC HE <u>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</u> NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> <u>Symptom::</u> CH ILL S	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: VO MITI NG Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry DIA RRH EA NO
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2.f Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry NEW OR WORSENE D MUSCL E PAIN NO

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031197**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04**2.g Symptom:**

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NEW OR WORSENER 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
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: NEW OR WORSENER ED JOINT PAIN Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NEW OR WORSENER JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Injection Site Reaction:: RED NES S Were injection site reactions pre NO sent on the last day the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Injection Site Reaction:: SWE LLIN G Were injection site reactions pr NO esent on the last day the Subjec t Diary was completed?:	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-05-2020 11:36:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031197**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-05-2020 11:34:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-05-2020 11:34:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-05-2020 12:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-05-2020 11:34:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-05-2020 11:34:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Collection: Oct/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-05-2020 12:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BPYL9D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 12:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BPYL9D	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: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

5.b

Date	Location	User	Value	Reason
Oct-05-2020 12:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNWKJB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 12:33:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNWKJB	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-05-2020 12:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNWKJC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 12:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNWKJC	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1003

Subject No: 10031197

Generated By: pfe.levissc

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-05-2020 11:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Oct/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-05-2020 11:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

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

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

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Date	Location	User	Value	Reason
Feb-09-2021 12:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Form Deleted	combine with SAE
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Form Created	

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Form Created	

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-06-2021 00:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	closing query on a deleted event
Feb-09-2021 12:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	combine with SAE
Feb-09-2021 11:50:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical See query on SAE of the same name; as the period of a SAE event when subject was outpatient & when it was Grade 1 can be covered by the SAE report (which must meet criteria at some time); please merge with SAE or rename this event
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: right ureteropelvic junction obstruction	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-05-2021 16:27:07	ACV0PFEINFP6000	auto query	Query 1: Closed	Close Auto Query

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		
Feb-05-2021 16:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jan/13/2021 13:19	Transcription Error
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For right ureteropelvic junction obstruction Start Date 13/Feb /2021, is a future date relative to when it was entered on 05/Feb /2021. Please correct.
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Feb/13/2021 13:19	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 11:45:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO End Date Time: Jan/27/2021 UNK:UNK	New Information
Feb-05-2021 16:56:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: YES	New Information
Feb-05-2021 16:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For right ureteropelvic junction obstruction End Date & Time 14/Jan/2021 UNK:UNK is before the Start Date & Time 13/Feb/2021 13:19.
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO End Date Time: Jan/14/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-06-2021 00:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	closing query on a deleted event
Feb-09-2021 12:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	combine with SAE
Feb-09-2021 11:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical COVID test status (yes/no) during Hosp /elective surgery was not reported in the SAE. Please submit a follow-up SAE form [#2021124061] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

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Form Status: Data Complete, Deleted

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Subject Initials: ---

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

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

Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> ureteropelvic junction obstruction	Initial Entry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-06-2021 00:13:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	closing query on a deleted event
Feb-09-2021 12:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-09-2021 12:26:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: YES	Transcription Error
Feb-09-2021 11:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Con Med is NO; however, SAE report states subject received analgesia. Please review, harmonize reporting, and update where applicable
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-08-2021 15:45:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_AE001_35
Feb-08-2021 11:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	end date is provided
Feb-06-2021 03:35:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7171746;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-05-2021 16:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> NO	Initial Entry

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Header Text: c4591001

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Subject No: 10031197

Generated By: pfe.levissc

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Form Status: Data Complete, Frozen

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1. Category:

Date	Location	User	Value	Reason
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-15-2021 08:02:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 7: Closed	Discrepancy has been closed.
Feb-15-2021 07:07:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Answered	Changed Information
Feb-15-2021 07:07:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Congenital right ur eteropelvic junctio n obstruction	Changed Information
Feb-12-2021 15:20:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe francm73)	Query 4: Closed	Response satisfies query
Feb-11-2021 19:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 7: Opened	Special Characters: Verbatim Term contains embedded non-compliant characters.
Feb-11-2021	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS	Query 6: Closed	Discrepancy has been

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Subject No: 10031197
Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
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17:35:29 (UTC-05:00) Eastern Time (US & Canada)		Oracle (pfe.PFETMS)		closed.
Feb-11-2021 14:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	Transcription Error
Feb-11-2021 14:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error
Feb-11-2021 14:47:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe mfrancis)	Data Entry: congenital right ureteropelvic junction obstruction	Transcription Error
Feb-11-2021 14:14:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe francm73)	Query 4: Reissued: Opened	DM1: congenital right ureteropelvic junction UPJ obstruction should be on one line. Please review and update as appropriate
Feb-11-2021 13:12:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 6: Opened	Special Characters: Verbatim Term contains embedded non-compliant characters.
Feb-11-2021 11:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 5: Closed	Discrepancy has been closed.
Feb-11-2021 09:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Transcription Error
Feb-11-2021 09:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Feb-11-2021 09:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: congenital right ure teropelvic junction obstruction	Transcription Error
Feb-10-2021 16:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 5: Opened	Special Characters: Verbatim Term contains embedded non-compliant characters.
Feb-10-2021 13:43:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 4: Opened	DM Q: congenital right ureteropelvic junction UPJ obstruction should be on one line. Please review and update as appropriate
Feb-10-2021 13:42:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Closed	Discrepancy has been closed.
Feb-10-2021 11:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Feb-10-2021 11:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: congenital right ure teropelvic junction UPJ obstruction	Changed Information
Feb-10-2021 11:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Opened	Special Characters: Verbatim Term contains embedded non-compliant characters.
Feb-10-2021 09:52:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.
Feb-10-2021 08:30:19 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

& Canada)				
Feb-10-2021 08:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe mfrancis)	Query 1: Deleted	Transcription Error
Feb-10-2021 08:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe mfrancis)	Data Entry: congenital right ure teropelvic junction UPJ obstruction	Transcription Error
Feb-09-2021 14:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Special Characters: Verbatim Term contains embedded non-compliant characters.
Feb-09-2021 13:17:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe noig)	Query 1: Reissued: Candidate	pending safety update
Feb-09-2021 13:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: congenital right ure teropelvic junction (UPJ) obstruction	clarified diagnosis and harmonized with SAE safety report
Feb-09-2021 12:40:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Query 1: Answered	merging AE's with a start date of 14 Dec 2020 will send new safety report with SAE starting on 14 Dec 2020
Feb-09-2021 10:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe noig)	Query 1: Opened	SAE RECON: Congenital right ureteropelvic junction (UPJ) obstruction(onset date:27Jan2021)was reported in safety database however AE in inform is "right ureteropelvic junction obstruction"(onset date:26Jan2021). Please confirm and update CRF or Safety DB.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: right ureteropelvic j unction obstruction	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Feb-09-2021 12:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Dec/1/2020 UNK:UNK	New Information
Feb-09-2021 12:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-09-2021 12:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Dec/14/2020 UNK:UNK	Transcription Error
Feb-09-2021 12:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For right ureteropelvic junction obstruction Start Date 14/Dec /2021, is a future date relative to when it was entered on 09/Feb /2021. Please correct.
Feb-09-2021 12:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Dec/14/2021 UNK:UNK	Changed Information
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jan/26/2021 16:13	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-23-2021 14:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-09-2021 12:46:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	combine AE's with a start date of 01 Dec 2020 will update safety SAE # 2021124061 to reflect more accurate start date

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1003
Subject No: 10031197
Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Status: Data Complete, Frozen
Site Name: (1003) Rochester Regional HealthRochester General Hospital
Subject Initials: ---
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Feb-09-2021 12:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-09-2021 12:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For right ureteropelvic junction obstruction End Date & Time 27/Jan/2021 UNK:UNK is before the Start Date & Time 14/Dec/2021 UNK:UNK.
Feb-09-2021 11:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical start date is 27Jan21; however SAE report states 'several wks flank pain prior to 20Dec20'. In Vaccine study, SAE start date is day event starts; not day it meets serious criteria (item 11 in vaccine SAE instruct); please review start date.
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO End Date Time: Jan/27/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-23-2021 14:32:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query

Header Text: c4591001

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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Feb-11-2021 15:02:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 2: Answered	SAE updated with COVID testing
Feb-10-2021 15:47:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp/surgery was not reported in the SAE. Please submit a follow-up SAE form [#2021124061] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Feb-10-2021 13:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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Header Text: c4591001

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Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-10-2021 11:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE congenital right ureteropelvic junction UPJ obstruction: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-10-2021 08:30:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE congenital right ureteropelvic junction UPJ obstruction : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-09-2021 13:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE congenital right ureteropelvic junction (UPJ) obstruction : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE right ureteropelvic junction obstruction : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: YES Is this serious event associated with	Initial Entry

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			congenital anomaly or birth defect? YES Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> ureteropelvic junction obstructio	Initial Entry

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Header Text: c4591001

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Subject No: 10031197

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-23-2021 14:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-11-2021 10:41:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-11-2021 10:41:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Changed Information
Feb-10-2021 15:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Con Med is NO; however, SAE report states subject received analgesia. Please review, harmonize reporting, and update where applicable
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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Header Text: c4591001

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Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-05-2021 17:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-10-2021 13:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Data Entry: 2021124061	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS -
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
Dec-18-2020 10:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneffenburger)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Dec-18-2020 10:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Dec-18-2020 10:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Dec-18-2020 10:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Dec-18-2020 10:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Data Entry: Quadrivalent Influenza Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Dec-18-2020 10:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Data Entry: Oct/UNK/2020	Initial Entry

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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

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Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levissc

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-17-2020 14:35:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: Dec/16/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

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
Dec-18-2020 07:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-18-2020 05:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-17-2020 14:36:06 (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.
Dec-17-2020 14:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneppenburger)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

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Header Text: c4591001

Visit: V101_VAX3

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Site No: 1003

Subject No: 10031197

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
Dec-17-2020 14:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: Dec/17/2020	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit
Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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I. Consent Was:

Date	Location	User	Value	Reason
Dec-17-2020 14:36:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: OBTAINED Date Written Consent Obtained Dec/17/2020	Initial Entry

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: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-18-2020 07:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: Dec/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-18-2020 07:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-18-2020 07:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031197**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
Dec-18-2020 07:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-18-2020 07:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-18-2020 12:13:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 07:52:42 (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.
Dec-18-2020 07:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: YES Date of Collection: Dec/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-18-2020 12:13:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BPYLCZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 12:13:54 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Madison Murphy	Data Entry: BPYLCZ	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

Generated By: pfe.levisse

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(US & Canada)		(pfe mmurphy)		
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5.b

Date	Location	User	Value	Reason
Dec-18-2020 12:14:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNWKN1	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 12:14:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNWKN1	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-18-2020 12:14:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNWKN2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 12:14:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNWKN2	Initial Entry

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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:** 10031197**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
Dec-18-2020 07:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-18-2020 07:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-18-2020 12:13:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 07:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-18-2020 07:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: YES Date of Collection: Dec/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-18-2020 12:13:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BPYLCS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 12:13:32 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Madison Murphy	Data Entry: BPYLCS	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

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(pfe mmurphy)

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Form Version: 10-Dec-2020 02:26

Site No: 1003

Subject No: 10031197

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
Dec-18-2020 07:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-18-2020 07:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-18-2020 07:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-18-2020 07:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: Dec/17/2020 14:53	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-18-2020 07:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-18-2020 07:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

Dec-18-2020 07:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Dec-18-2020 07:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Dec-18-2020 07:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-18-2020 07:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Dec-18-2020 07:53:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: YES	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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
Dec-18-2020 07:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: Dec/16/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-18-2020 07:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-06-2021 15:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jan/6/2021	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:** 10031197**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
Jan-06-2021 13:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-06-2021 13:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-06-2021 13:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-06-2021 13:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-06-2021 13:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: YES Date of Collection: Jan/6/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-06-2021 13:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BPYLGS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-06-2021 13:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BPYLGS	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1003

Subject No: 10031197

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
Jan-06-2021 16:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-06-2021 16:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-06-2021 16:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-06-2021 16:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jan/6/2021 14:25	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-06-2021 16:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-06-2021 16:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-06-2021 16:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Jan-06-2021 16:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-06-2021 16:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-06-2021 16:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Jan-06-2021 16:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: YES	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031197

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-09-2021 15:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_SV001_11
Feb-09-2021 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Ans wered	Changed data per query
Feb-09-2021 08:19:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW7195178;V103 Visit Date is entered, but Disposition - Treatment form at FURTHER_VACCINATION_EOT visit is not completed. Please review and update as appropriate.
Feb-08-2021 13:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry : Feb/5/ 2021	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031197

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
Feb-08-2021 13:55:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-08-2021 13:55:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Contact: Feb/5/2021	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031197

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-10-2021 01:23:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Adarsh Prabhu (pfe.prabha11)	Query 3: Closed	Incorrect query
Feb-09-2021 16:36:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Opened	DMW7210903;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-09-2021 08:33:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Feb/5/2021	Initial Entry
Jan-18-2021 20:03:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Closed	Response satisfies query
Jan-15-2021 16:00:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Closed	Auto closed by Validation Check: VC_DS001_21
Jan-15-2021 12:09:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Jan-15-2021 12:09:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-15-2021 12:09:59	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry:	Transcription Error

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031197**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)				
Jan-14-2021 21:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Open ed	DMW6841946;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Jan-10-2021 19:51:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hui Pan (pfe.panh18)	Query 1: Open ed	ClinQuery: The treatment period is defined as vax3 visit through the 1-month post vaccination visit after vax4. EOT date should therefore match date of visit at visit 103. Please review.
Jan-06-2021 16:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jan/6/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-09-2021 08:33:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry
Jan-15-2021 12:09:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Jan-06-2021 16:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-09-2021 08:33:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1003

Subject No: 10031197

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT - 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

Jan-28-2021 13:16:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Jan-28-2021 10:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-28-2021 10:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry:	Transcription Error
Jan-28-2021 01:30:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: As subject is in follow up phase kindly consider removing data from this field. Thank you.
Jan-06-2021 16:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031197

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
Oct-05-2020 11:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-13-2020 15:40:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-13-2020 15:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-05-2020 11:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/5/2020	Initial Entry
Aug-13-2020 15:40:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/13/2020	Initial Entry
Aug-13-2020 15:40:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/13/2020	Initial Entry

090177e196ae3d6b\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031197

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
Sep-12-2020 11:21:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Edward Walsh (pfe.ewalsh)	Data Entry: Click Here to Enable	Initial Entry