

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/3/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10051214]
2.	Birth Date:	(b) (6) /1949
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic obstructive pulmonary disease]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SWELLING OF FEET]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HIGH BLOOD PRESSURE]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MENOPAUSE]
	Start Date:	UNK/UNK/1994
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[TYPE II DIABETES]
	Start Date:	Feb/UNK/2020
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HIGH CHOLESTEROL]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DEPRESSION]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/3/2020
2.	Weight:	[243.8]
3.	Unit:	LB
4.	Height:	[68.0]
5.	Unit:	in
6.	Body Mass Index:	[37.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[95.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/3/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/3/2020
2.	Randomization Number:	[251636]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: 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	[BKNW7V]
5.b	Sample ID	[BKNW7T]
5.c	Sample ID	[BKNW7W]
5.d	Sample ID	[BK07XS]
5.e	Sample ID	[BK07XR]

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: 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	[BJH85J]
-----	-----------	----------

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/3/2020 15:14
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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	---	--

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/22/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/22/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/22/2020
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	[BM5F8G]
-----	-----------	----------

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Vaccination

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BJ3WJ8]
5.b	Sample ID	[BJ3WJ7]
5.c	Sample ID	[BPTZ5H]
5.d	Sample ID	[BPTZ5J]
5.e	Sample ID	[BPTZ5K]

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

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: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

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: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Sep/13/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

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: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	UPPER RESPIRATORY INFECTION	Sep/6/2020 UNK:UNK	NO End Date Time: Sep/16/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	FACIAL SWELLING	Sep/6/2020 UNK:UNK	NO End Date Time: Sep/16/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	FACIAL TENDERNESS	Sep/6/2020 UNK:UNK	NO End Date Time: Sep/16/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	INJECTION SITE PAIN	Sep/4/2020 UNK:UNK	NO End Date Time: Sep/7/2020 UNK:UNK	Repeating Pages

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[UPPER RESPIRATORY INFECTION]
4.	Start Date Time:	Sep/6/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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: [CONCURRENT ILLNESS]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[FACIAL SWELLING]
4.	Start Date Time:	Sep/6/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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: [ALLERGIC REACTION TO UNKNOWN AGENT]

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001		
Visit: Logs - Unscheduled		Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02		Form Status: Data Complete, Locked, Frozen
Site No: 1005		Site Name: (1005) Rochester Clinical Research, Inc.
Subject No: 10051214		Subject Initials: ---
Generated By: pfe.levisse		Generated Time (GMT): 29-Mar-2021 04:04
Back to Form eCRF Audit Trail History Form Audit Trail		
Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[FACIAL TENDERNESS]
4.	Start Date Time:	Sep/6/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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: [ALLERGIC REACTION TO UNKNOWN AGENT]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[INJECTION SITE PAIN]
4.	Start Date Time:	Sep/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/7/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001	Form: ADVERSE EVENT REPORT
Visit: Logs - Unscheduled	Form Status: Data Complete, Locked, Frozen
Form Version: 22-Apr-2020 21:02	Site Name: (1005) Rochester Clinical Research, Inc.
Site No: 1005	Subject Initials: ---
Subject No: 10051214	Generated Time (GMT): 29-Mar-2021 04:04
Generated By: pfe.levisse	

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Medication Error

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Vaccination

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/14/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/14/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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

Withdrawal Of Consent

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Sep/13/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1005

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

Subject No: 10051214

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

Name	Signature Meaning	Date	Type	Action
Matthew Davis	Approved	Mar-12-2021 12:33:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-03-2020 16:16:12 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Not Applicable

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
7	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
8	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
9	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
10	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
11	Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	SUBJECT NOT RECIEVIING SECOND INJECTION <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, Signed, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Matthew Davis	Approved	Mar-12-2021 12:33:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Julie Mooney	N/A	Feb-24-2021 08:35:29 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
--------------	-----	---	--	-----------------------------------

Affidavit:

N/A

Matthew Davis	Approved	Jan-22-2021 09:33:54 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

Affidavit:

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

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

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

Chelsey LoMonaco	N/A	Jan-21-2021 18:23:57 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
------------------	-----	---	--	-----------------------------------

Affidavit:

N/A

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levisse

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

Matthew Davis	Approved	Jan-21-2021 15:37:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

Affidavit:

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

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

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

Liam Sullivan	N/A	Jan-20-2021 11:07:50 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------------	-----	---	--	-----------------------------------

Affidavit:

N/A

Matthew Davis	Approved	Oct-26-2020 12:59:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

Affidavit:

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

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

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

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-03-2020 16:15:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:15:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Sep-03-2020 16:15:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: OBTAINED Date Written Consent Obtained Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-03-2020 16:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10051214	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1949	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-03-2020 16:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-03-2020 16:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	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
Sep-03-2020 16:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: WHITE	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Sep-30-2020 07:39:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Per site monitor will note deviation
Sep-29-2020 05:33:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Reissued:Candidate	Added to DM Ops tracker. Kindly review the Ops tracker and take appropriate action.
Sep-28-2020 13:46:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	per PI, swab not needed
Sep-28-2020 13:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sonali shah (pfe.shahs132)	Query 1: Opened	As per Illness ediary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 10SEP2020. But there is no COVID Illness visit reported in the database. Please clarify.
Sep-03-2020 16:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/3/2020	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-03-2020 16:16:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-03-2020 16:16:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-03-2020 16:16:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1005**Subject No:** 10051214**Generated By:** pfe.levissc**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Sep-03-2020 16:17:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical Hist Chronic obstructive ory Term: pulmonary disease Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:17:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 16:17:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Chronic obstructive pulmonary d isease	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:17:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/2018	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:17:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

1.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-03-2020 16:18:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 er: Medical History SWELLING OF Term: FEET Start Date: UNK/UNK/200 0 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: SWELLING OF FEET	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/2000	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-03-2020 16:18:24	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Line/MH Number: Medical History Term: Start Date: Ongoing:	3 HIGH BLOOD PRESSURE UNK/UNK/2000 YES
--	--	------------	---	---

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: HIGH BLOOD PRESSURE	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/2000	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-03-2020 16:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number:	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			Medical History Term: Gastroesophageal reflux disease Start Date: UNK/UNK/2000 Ongoing: YES	
--	--	--	--	--

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Gastroesophageal reflux disease	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/2000	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-03-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: MENOPAUS E Start Date: UNK/UNK/1994	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			Ongoing:	YES	
--	--	--	-----------------	-----	--

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: MENOPAUSE	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/1994	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-03-2020 16:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: TYPE II DIAB ETES Start Date: Feb/UNK/2020 Ongoing: YES	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: TYPE II DIABETES	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Feb/UNK/2020	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Sep-03-2020 16:19:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History HIGH CHOLESTEROL Term: TEROL Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: HIGH CHOLESTEROL	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/2000	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

1.h

Date	Location	User	Value	Reason
Sep-03-2020 16:19:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: DEPRESSIO N Start Date: UNK/UNK/2 015 Ongoing: YES	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: DEPRESSION	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/2015	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 243.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 68.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	Data Entry: 37.1	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

7.a

Date	Location	User	Value	Reason
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Record Identifier 1 : Temperature: 95.5 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 16:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Sep-03-2020 16:25:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	NCS PER PI
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 95.5 F is outside of Normal Range 97 - 99.5 F.
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 95.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: F	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/3/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-03-2020 16:20:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-03-2020 16:20:15 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
--------------------	--	--	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT DONE	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-03-2020 16:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 251636	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051214**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-03-2020 16:24:10 (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 16:24:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 16:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:24:10 (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 16:24:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BKNW7V	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:24:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BKNW7V	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 16:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BKNW7T	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BKNW7T	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 16:24:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BKNW7W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:24:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BKNW7W	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-03-2020 16:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BK07XS	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BK07XS	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-03-2020 16:24:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BK07XR	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:24:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BK07XR	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:24:57 (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 16:24:57 (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 16:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:24:57 (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 16:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BJH85J	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BJH85J	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-03-2020 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 16:25:23 (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 16:25:23 (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 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/3/2020 15:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:25:23 (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 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: LEFT	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-03-2020 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-03-2020 16:25:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Sep-22-2020 16:10:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/22/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/22/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-22-2020 16:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Record Identifier 1 :: Temperature: 98.5 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 98.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: F	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/22/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-22-2020 16:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-22-2020 16:13:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE
--------------------	--	--	--

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 16:13:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT DONE	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051214**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-22-2020 16:13:48 (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-22-2020 16:13:48 (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-22-2020 16:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 16:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 16:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES Date of Collection: Sep/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-22-2020 16:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BM5F8G	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 16:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BM5F8G	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-25-2020 04:42:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sakshi Sarmalkar LDM (pfe.sarmas06_Idm)	Query 1 : Closed	Response satisfies query
Sep-24-2020 06:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1 : Answered	THE VACCINATION IS NOT GETTING ADMINISTERED
Sep-24-2020 01:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1 : Reissued: Opened	DM: Thank you for confirmation. kindly consider to respond the query once the vaccination is administer and update the data.
Sep-23-2020 07:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1 : Answered	THIS SUBJECT WAS NOT VACCINATED AT V2 AND WILL NOT BE RESCHEDULED FOR IT DUE TO AE
Sep-23-2020 02:11:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1 : Opened	DMW4781434;Temp Delay is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

(US & Canada)				
---------------	--	--	--	--

2. Treatment Name

Date	Location	User	Value	Reason
Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Not Applicable	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Not Applicable	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-26-2020 02:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 1 : Closed	Response satisfies query
Sep-25-2020 09:02:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1 : Answered	EOT PAGE UPDATED
Sep-25-2020 04:43:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sakshi Sarmalkar LDM (pfe.sarmas06_idm)	Query 1 : Reissued: Opened	DM1: Thank for the response. However, on EOT page Status is selected as VACCINATION COMPLETED. Please review and update correct EOT reason, else clarify.
Sep-24-2020 06:53:30	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1 : Answered	THE VACCINATION IS

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)			red	NOT GETTING ADMINISTERED
Sep-24-2020 01:47:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1 : Reissu ed:Open ed	DM: Thank you for confirmation. kindly consider to respond the query once the vaccination is administer and update the data.
Sep-23-2020 07:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1 : Answe red	THIS SUBJECT WAS NOT VACCINATED AT V2 AND WILL NOT BE RESCHEDULED FOR IT DUE TO AE
Sep-23-2020 02:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1 : Opene d	DMW4781439;Dose Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data E ntry: Not Ap plicable	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Not Applicable	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Not Applicable	Initial Entry
---	-----------------	--	--------------------------------------	---------------

7. Route:

Date	Location	User	Value	Reason
Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Not Applicable	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Not Applicable	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Not Applicable	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Not Applicable	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-22-2020 16:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Not Applicable	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-20-2020 16:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Oct/20/2020	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:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051214**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-20-2020 16:23:59 (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-20-2020 16:23:59 (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-20-2020 16:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 16:23:59 (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-20-2020 16:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 16:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BJ3WJ8	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: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BJ3WJ8	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 16:24:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BJ3WJ7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:24:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BJ3WJ7	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 16:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BPTZ5H	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:24:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BPTZ5H	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-20-2020 16:24:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BPTZ5J	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (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: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:24:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BPTZ5J	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-20-2020 16:24:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BPTZ5K	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:24:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BPTZ5K	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-24-2020 06:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-24-2020 06:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-25-2020 11:49:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Mathias (pfe.mathij15)	Query 1: Closed	Response satisfies query
Sep-25-2020 09:00:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	the subject is still in the study, just did not receive second dose
Sep-25-2020 09:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Sep-25-2020 09:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: ADVERSE EVENT	Transcription Error
Sep-24-2020 06:55:52 (UTC-05:00) Eastern	ACV0PFEINFP6000	Chelsey LoMonaco	Data Entry: COMPLETED	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)

(pfe.clomonaco)

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-08-2020 15:55:57 (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
Sep-08-2020 15:55:57 (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
Sep-20-2020 15:54:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Closed	Response satisfies query
Sep-17-2020 12:09:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	PER PI, MONITOR AND PROTOCOL A SWAB IS NOT NEEDED
Sep-16-2020 22:52:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Reissued:Opened	Clin: Please COVID-19 related event UPPER RESPIRATORY INFECTION must trigger a COVID Illness Visit regardless of other potential diagnosis determination per protocol and a NASAL SWAB needs to be collected ASAP.
Sep-14-2020 16:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	does not qualify for a swab

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Sep-14-2020 10:20:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: Per PA-5 - Sections 8.3.7. and 8.13., COVID-19 related event UPPER RESPIRATORY INFECTION should trigger a COVID Illness Visit regardless of other potential diagnosis and a NASAL SWAB needs to be collected ASAP.
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UPPER RESPIRATORY INFE CTION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/6/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-22-2020 16:17:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO End Date Time: Sep/16/2020 UNK:UNK	Transcription Error
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-13-2020 18:36:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 1: Closed	Response satisfies query

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Sep-10-2020 09:58:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	UPDATED TO 'UNRELATED'
Sep-09-2020 20:56:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 1: Opened	ClinQuery: This AE has a toxicity grade of 2, but has been deemed related, please confirmed that an unplanned visit is to be scheduled
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	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
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-15-2020 06:04:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Response satisfies query

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1005**Subject No:** 10051214**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Sep-14-2020 16:25:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	PER PI, THIS IS NOT RELATED
Sep-14-2020 12:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: Please confirm casualty as all other AEs with same start date are considered related.
Sep-10-2020 09:58:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT RELATED If Not Related to study treatme nt(s), this event is due to: OTHER <i>If Other, specify:</i> CONCURRENT ILLNES S	Transcription Error
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-15-2020 06:05:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Response satisfies query
Sep-14-2020 16:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	PER SUBJECT, THEY TOOK BENADRYL
Sep-14-2020 12:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: Please clarify what treatment was given for this AE

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry
---	-----------------	--	---------------------------	---------------

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 16:18:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 16:18:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Sep-22-2020 16:17:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE UPPER RESPIRATORY INFECTION: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT RECOVERED/NOT RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 15:55:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-11-2020 09:08:36 (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
Sep-11-2020 09:08:36 (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
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: FACIAL SWELLING	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/6/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-22-2020 16:17:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO End Date Time: Sep/16/2020 UNK:UNK	Transcription Error
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	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
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 11:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Response satisfies query
Sep-16-2020 11:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-16-2020 11:16:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Transcription Error

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

			<i>If Other, specify:</i> ALLERGIC REACTION TO UNKNOWN AGENT	
Sep-15-2020 10:36:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: We would appreciate some clarification regarding causality and why this AE is considered related to the vaccine.
Sep-11-2020 09:55:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: RELATED	Transcription Error
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-25-2020 15:08:24 (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_32
Sep-25-2020 09:01:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	UPDATED EOT PAGE
Sep-25-2020 02:57:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4806940;The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Disposition-Treatment Form Status is not DEATH OR

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

				ADVERSE EVENT. Please review and update as appropriate.
Sep-22-2020 16:28:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: DRUG WITHD RAWN	New Information
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT AP PLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 16:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 16:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Sep-22-2020 16:17:52 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE FACIAL SWELLING:

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Time (US & Canada)				Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 09:08:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-11-2020 09:10:32 (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
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: FACIAL TENDERNESS	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/6/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-22-2020 16:18:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO End Date Time: Sep/16/2020 UNK:UNK	Transcription Error
Sep-22-2020 16:18:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO End Date Time:	Transcription Error

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

			Sep/7/2020 UNK:UNK	
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	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
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 11:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Response satisfies query
Sep-16-2020 11:16:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1005**Subject No:** 10051214**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Sep-16-2020 11:16:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> ALLERGIC REACTION TO UNKNOWN AGENT	New Information
Sep-15-2020 10:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: We would appreciate some clarification regarding causality and why this AE is considered related to the vaccine.
Sep-11-2020 09:55:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: RELATED	Transcription Error
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-25-2020 15:08:24 (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_32
Sep-25-2020 09:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	UPDATED EOT PAGE
Sep-25-2020 02:56:55 (UTC-05:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4806941;The Latest Action to Study Treatment is

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Eastern Time (US & Canada)				DRUG WITHDRAWN, but the Disposition-Treatment Form Status is not DEATH OR ADVERSE EVENT. Please review and update as appropriate.
Sep-22-2020 16:28:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: DRUG WITHDRAWN	Transcription Error
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 16:19:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Sep-22-2020 16:19:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Sep-22-2020 16:18:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE FACIAL TENDERNESS: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT RECOVERED/NOT RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 09:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (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
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: INJECTION SITE PAIN	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO End Date Time: Sep/7/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 2	Initial Entry
---	-----------------	--	-------------------------	---------------

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	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
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	Chelsey LoMonaco	Data Entry: NO	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

Time (US & Canada)

(pfe.clomonaco)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1005

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

Subject No: 10051214

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 11:07:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Liam Sullivan (pfe.lisullivan)	Data Entry: Jan/14/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-24-2021 08:35:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed t o have received only placebo at Vaccination 1/2	Transcription Error
Jan-20-2021 11:08:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Liam Sullivan (pfe.lisullivan)	Data Entry: Participant is NOT willing to retu rn for Vaccination 3 OR otherwis e not eligible	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-20-2021 11:07:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Liam Sullivan (pfe.lisullivan)	Data Entry: Jan/14/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-24-2021 16:33:03 (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_35
Feb-24-2021 08:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	Changed data per query
Feb-22-2021 10:08:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Opened	DMW7349646;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Jan-22-2021 01:37:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

Canada)				
Jan-21-2021 18:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Initial Entry
Jan-21-2021 18:23:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry : ASSE SS EL IGIBI LITY FOR ADDI TION AL V ACCI NATI ON	Initial Entry
Jan-21-2021 02:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Op ened	DM: Please complete this item. Thank you.

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Sep-25-2020 09:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Transcription Error
Sep-24-2020 06:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-03-2020 16:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 16:16:27 (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
Sep-25-2020 09:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/13/2020	Transcription Error
Sep-24-2020 06:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/13/2020	Initial Entry
Sep-03-2020 16:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry
Sep-03-2020 16:16:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry

090177e196ae2f6e\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051214

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-26-2020 12:28:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Click Here to Enable	Initial Entry