

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/14/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10051069]
2.	Birth Date:	(b) (6)/1952
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:** 10051069

**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	Aug/14/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

**Form:** INCLUSION/EXCLUSION CRITERIA

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

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

**Subject Initials:** ---

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

**Form Comments**

**Inclusion Criteria Not Met**

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

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

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

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

**Site No:** 1005

**Subject No:** 10051069

**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	Aug/14/2020
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:** 10051069

**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:	[MENOPAUSE]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HIGH BLOOD PRESSURE]
	Start Date:	UNK/UNK/2004
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LEFT BREAST LUMPECTOMY]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LEFT BREAST CANCER]
	Start Date:	UNK/UNK/2005
	Ongoing:	NO End Date: UNK/UNK/2010

090177e196ae2f6f\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:** 10051069

**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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[controlled squamous cell carcinoma skin on chin]
	Start Date:	UNK/UNK/1993
	Ongoing:	YES



**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/14/2020
2.	Weight:	[142.0]
3.	Unit:	LB
4.	Height:	[61.0]
5.	Unit:	in
6.	Body Mass Index:	[26.8]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[96.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051069

**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:	Aug/14/2020
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

090177e196ae2f6f\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:** 10051069

**Generated By:** pfe.lewissc

**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 :	Aug/14/2020
2.	Randomization Number:	[228557]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8PKL]
5.b	Sample ID	[BM8PKN]
5.c	Sample ID	[BM8PKM]
5.d	Sample ID	[BLCZ9L]
5.e	Sample ID	[BLCZ9M]

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**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051069

**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: Aug/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BKNWFJ]
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090177e196ae2f6f\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:** 10051069

**Generated By:** pfe.lewissc

**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:	Aug/14/2020 09:34
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051069

**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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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090177e196ae2f6f\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:** 10051069

**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	Sep/2/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.lewissc

**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/2/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051069

**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/2/2020
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

090177e196ae2f6f\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:** 10051069

**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/2/2020
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	[BKNVRW]
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090177e196ae2f6f\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:** 10051069

**Generated By:** pfe.lewissc

**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/2/2020 15:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae2f6f\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:** 10051069

**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/2/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Sep/8/2020
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/2/2020
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	[BJ3W4N]
5.b	Sample ID	[BJ3W4P]
5.c	Sample ID	[BP9ZXN]
5.d	Sample ID	[BP9ZXP]
5.e	Sample ID	[BP9ZXR]

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled **Form:** DATE OF VISIT - ILLNESS ONSET Visit

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Visit:** POT\_COVID\_ILL - New Unscheduled **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 Visit

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:** 10051069

**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	[ ]
----	-----------	-----

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB Visit

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**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	[ ]
----	-----------	-----

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled **Form:** HEALTH CARE UTILIZATION  
Visit

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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?	
----	--	--

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled **Form:** ILLNESS DETAILS  
Visit

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**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	[ ]
----	-----------	-----

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)



**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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.leviscc

**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	LEFT BREAST CANCER	Sep/4/2020 UNK:UNK	NO End Date Time: Jan/12/2021 00:00	<a href="#">Repeating Pages</a>

090177e196ae2f6\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: 10051069

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Complete

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

Subject Initials: ---

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

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[LEFT BREAST CANCER]
4.	Start Date Time:	Sep/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 00:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? NO  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae2f6f\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:** 10051069

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

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

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

**Subject Initials:** ---

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

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: [PRE-EXISTING OCCULT MALIGNANCY]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[2020366988]

090177e196ae2f6\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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Medication Error**

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

090177e196ae2f6f\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:** 10051069

**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	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:	//

090177e196ae2f6f\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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051069

**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

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**Concomitant Medications**

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

090177e196ae2f6\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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

**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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levisc

**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:** 10051069    **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:** 10051069    **Subject Initials:** ---

**Generated By:** pfe.lewissc    **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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:	

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)



**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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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?	

090177e196ae2f6f\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:** 10051069

**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:** 10051069

**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:** 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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/13/2021
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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051069

**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/13/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:** V101\_VAX3

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**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](#)

**Date of Visit**

1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.lewissc

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**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](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/18/2021
----	--------------	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Jan/18/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 14-Jan-2021 02:21

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:	Jan/18/2021
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

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRL2SM]
5.b	Sample ID	[BRL2SN]
5.c	Sample ID	[BRL2SP]
5.d	Sample ID	[BS32XH]
5.e	Sample ID	[BS32XJ]

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

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

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRF81R]
-----	-----------	----------

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.lewissc

**Form:** VACCINATION

**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](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/18/2021 14:49
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**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](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 14-Jan-2021 02:21

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:	Feb/8/2021
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

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.lewissc

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

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRN01N]
-----	-----------	----------

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.lewissc

**Form:** VACCINATION

**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**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/8/2021 15:38
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1005

**Subject No:** 10051069

**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:** V103\_MONTH1

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1005

**Subject No:** 10051069

**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:** V104\_MONTH6

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1005

**Subject No:** 10051069

**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:** V105\_MONTH18

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.lewissc

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

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

**Form:** DISPOSITION - TREATMENT

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051069

**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	FOLLOW-UP
2.	Subject Status Date	Oct/2/2020

**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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
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**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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

**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	Aug-14-2020 08:08:04 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

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

**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](#)

Item	Date	User	Comment
Form	Jan-19-2021 07:50:51 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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 10:42:03 (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.

Jessica Fisher	N/A	Mar-12-2021 10:13:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Davis	Approved	Mar-12-2021 09:18:31 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

Chelsey LoMonaco	N/A	Feb-01-2021 07:12:04 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae2f6f\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:** 10051069**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04**Affidavit:**

N/A

Matthew  
Davis

Approved

Jan-20-2021 08:54:49 (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-19-2021 07:49:18 (UTC-05:00) Eastern  
Time (US & Canada)Edit - All  
signatures  
invalidated**Affidavit:**

N/A

Matthew  
Davis

Approved

Oct-08-2020 10:05:31 (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

Oct-02-2020 11:22:15 (UTC-05:00) Eastern  
Time (US & Canada)Edit - All  
signatures  
invalidated**Affidavit:**

N/A

Matthew  
Davis

Approved

Sep-23-2020 16:06:20 (UTC-05:00) Eastern  
Time (US & Canada)

BOOK

Signed

**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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Affidavit:**

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

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

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

Ricell Ann Piojo	N/A	Sep-23-2020 05:14:01 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Davis	Approved	Sep-22-2020 10:33:37 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

Chelsey LoMonaco	N/A	Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Matthew Davis	Approved	Sep-10-2020 10:38:59 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae2f6\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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Affidavit:**

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

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-14-2020 08:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 08:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2f6f\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:** 10051069

**Generated By:** pfe.lewissc

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

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

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

**Subject Initials:** ---

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

[Back to Form](#)

***I. Consent Was:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-14-2020 08:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b><u>Data Entry:</u></b> OBTAINED Date Written Consent Obtained  Aug/14/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1005

Subject No: 10051069

Generated By: pfe.lewissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-14-2020 08:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10051069	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-14-2020 08:07:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1952	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-14-2020 08:07:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-14-2020 08:07:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORI GIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 08:07:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2f6\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:** 10051069

**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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-14-2020 08:07:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Aug/14/2020	Initial Entry



**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.lewissc

**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

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

Date	Location	User	Value	Reason
Aug-14-2020 08:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Aug/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-14-2020 08:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-14-2020 08:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f6f\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: 10051069

Generated By: pfe.lewissc

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

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*1.a*

Date	Location	User	Value	Reason
Aug-14-2020 09:27:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> <b>r:</b> <b>Medical History</b> MENOPAU <b>Term:</b> SE <b>Start Date:</b> UNK/UNK/ 2002 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-14-2020 09:27:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 09:27:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> MENOPAUSE	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Aug-14-2020 09:27:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/2002	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
Aug-14-2020 09:27:44	ACV0PFEINFP6000	Chelsey	<b>Data Entry:</b>	Initial Entry

090177e196ae2f6\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:** 10051069  
**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

(UTC-05:00) Eastern Time (US & Canada)		LoMonaco (pfe.clomonaco)	YES	
--	--	--------------------------	-----	--

*1.b*

Date	Location	User	Value	Reason
Aug-14-2020 09:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 2 <b>mber:</b> <b>Medical History Term:</b> HIGH BLOOD PRESSURE <b>Start Date:</b> UNK/UNK/2004 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f6\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: 10051069

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.b Line/MH Number:***

Date	Location	User	Value	Reason
Aug-14-2020 09:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 09:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> HIGH BLOOD PRESSURE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 09:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/2004	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Aug-14-2020 09:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Aug-14-2020 09:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> LEFT BREAST LUMPECTOMY <b>Start Date:</b> UNK/UNK/2010	Initial Entry

090177e196ae26f6\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: 10051069

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

			<b>Ongoing:</b> NO End Date:  UNK/UNK/20 10	
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***I.c Line/MH Number:***

Date	Location	User	Value	Reason
Aug-14-2020 09:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 09:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> LEFT BREAST LUMPECT OMY	Initial Entry

***I.c Start Date:***

Date	Location	User	Value	Reason
Aug-14-2020 09:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

***I.c Ongoing:***

Date	Location	User	Value	Reason
Aug-14-2020 09:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2010	Initial Entry

***I.d***

Date	Location	User	Value	Reason
Aug-14-2020 09:30:05	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae2f6f\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: 10051069

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: 4 Medical History Term: LEFT BREAST CANCER Start Date: UNK/UNK/2005 Ongoing: NO End Date: UNK/UNK/2010	
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**1.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-14-2020 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-14-2020 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> LEFT BREAST CANCER	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Aug-14-2020 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Aug-14-2020 09:30:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO End Date: UNK/UNK/2010	Initial Entry

090177e196ae2f6\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:** 10051069

**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

*I.e*

Date	Location	User	Value	Reason
Aug-17-2020 06:19:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Line/M</b> 5 <b>H Numb</b> <b>er:</b> <b>Medical</b> controlled squam <b>History</b> ous cell carcino <b>Term:</b> ma skin on chin <b>Start Da</b> UNK/UNK/1993 <b>te:</b> <b>Ongoing</b> YES :	Transcription Error
Aug-14-2020 09:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 5 <b>Number:</b> <b>Medical</b> controlled squa <b>History T</b> mous cell skin <b>erm:</b> on chin <b>Start Date</b> UNK/UNK/199 : 3 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f6\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:** 10051069

**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

***I.e Line/MH Number:***

Date	Location	User	Value	Reason
Aug-14-2020 09:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 07:41:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-17-2020 06:19:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-17-2020 06:19:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> controlled squamous cell carcinoma skin on chin	Transcription Error
Aug-14-2020 12:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify CONTROLLED SQUAMOUS CELL SKIN ON CHIN as follows...Term is unclear. Are you reporting CONTROLLED SQUAMOUS CELL

090177e196ae2f6f\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: 10051069

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

				CARCINOMA SKIN ON CHIN? Or other? Please update the verbatim term to clarify. Thank you.
Aug-14-2020 09:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> controlled squamous cell skin on chin	Initial Entry

*1.e Start Date:*

Date	Location	User	Value	Reason
Aug-14-2020 09:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/1993	Initial Entry

*1.e Ongoing:*

Date	Location	User	Value	Reason
Aug-14-2020 09:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1005

Subject No: 10051069

Generated By: pfe.lewissc

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

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**1. Date:**

Date	Location	User	Value	Reason
Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Aug/14/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 142.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 61.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1005

Subject No: 10051069

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

Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 26.8	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 96.6 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-17-2020 01:00:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Response satisfies query
Aug-14-2020 09:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	NCS PER PI
Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.6 F is outside of Normal Range 97 - 99.5 F.
Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 96.6	Initial Entry

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051069

**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

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-14-2020 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-14-2020 09:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-14-2020 09:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-14-2020 09:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Aug/14/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-14-2020 09:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-14-2020 09:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

090177e196ae2f6f\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:** 30-Jul-2020 21:27

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Date	Location	User	Value	Reason
Aug-14-2020 09:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> : 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-14-2020 09:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-14-2020 09:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Aug-14-2020 09:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae2f6\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:** 10051069

**Generated By:** pfe.lewissc

**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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-14-2020 09:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Aug/14/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-14-2020 09:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 228557	Initial Entry

090177e196ae2f6\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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-14-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-14-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-14-2020 09:06:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-14-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-14-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Date of Collection:  Aug/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2f6\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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Aug-14-2020 09:06:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BM8PKL	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 09:06:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BM8PKL	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Aug-14-2020 09:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BM8PKN	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 09:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BM8PKN	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-14-2020 09:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BM8PKM	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 09:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BM8PKM	Initial Entry

090177e196ae2f6f\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:** 10051069

**Generated By:** pfe.levisse

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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.d**

Date	Location	User	Value	Reason
Aug-14-2020 09:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BLCZ9L	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 09:07:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BLCZ9L	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-14-2020 09:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BLCZ9M	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 09:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BLCZ9M	Initial Entry

090177e196ae2f6f\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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-14-2020 09:07:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-14-2020 09:07:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-14-2020 09:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-14-2020 09:07:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-14-2020 09:07:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Date of Collection:  Aug/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2f6\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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Aug-14-2020 09:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BKNWFJ	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-14-2020 09:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BKNWFJ	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051069

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

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

Date	Location	User	Value	Reason
Aug-14-2020 10:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-14-2020 10:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-14-2020 10:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-14-2020 10:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Aug/14/2020 09:34	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-14-2020 10:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae2f6f\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:** 10051069

**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

Aug-14-2020 10:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RIGHT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Aug-14-2020 10:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-14-2020 10:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-14-2020 10:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f6\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:** 10051069

**Generated By:** pfe.lewissc

**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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-14-2020 10:10:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FO R THIS SUBJECT	Initial Entry

090177e196ae2f6f\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:** 10051069

**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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-02-2020 15:48:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Sep/2/2020	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
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090177e196ae26f\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 30-Jul-2020 21:30

Site No: 1005

Subject No: 10051069

Generated By: pfe.levisse

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - 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-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E <b>Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:</b>	Initial Entry
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**2.b Symptom:**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was comple ted?:</b>	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**2.c Symptom:**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**2.d Symptom:**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</b> NO	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levissc

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

2.e Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA <b>Were fever or systemi</b> NO <b>c symptoms present o</b> <b>n the last day the Subj</b> <b>ect Diary was complet</b> <b>ed?:</b>	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levissc

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENE MUSCL E PAIN  <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was comple</b> <b>ted?:</b>	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEW OR WORSENERED MU SCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENERED JOINT P AIN  <b>Were fever or syst NO emic symptoms p resent on the last day the Subject D iary was complete d?:</b>	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEW OR WORSENERD JOI NT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RIGHT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Injection Site Reactio n:: RE DN ES S	Initial Entry

090177e196ae26f\Final\Final On: 01-Apr-2021 03:43 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Injection Site Reactions: SWELLING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJ ECTI ON SI TE <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1005

Subject No: 10051069

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> 98.1 <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 98.1	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:53	ACV0PFEINFP6000	Chelsey	<b>Data Entry:</b>	Initial Entry

090177e196ae26f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051069

**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

(UTC-05:00) Eastern Time (US & Canada)		LoMonaco (pfe.clomonaco)	F	
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**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-02-2020 15:49:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Sep/2/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

090177e196ae2f6f\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Sep-02-2020 15:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> 113 : <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae2f6\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:** 10051069**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-02-2020 15:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-02-2020 15:50:11 (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-02-2020 15:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Date of Collection:  Sep/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Sep-02-2020 15:50:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BKNVRW	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BKNVRW	Initial Entry

090177e196ae2f6\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: 10051069

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Sep-02-2020 15:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Sep/2/2020 15:50	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae2f6\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:** 10051069

**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-02-2020 15:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RIGHT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-02-2020 15:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 15:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f6\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:** 10051069

**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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-02-2020 11:22:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Oct/2/2020	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051069**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> FE V ER  <b>Were fever or systemic N</b> <b>symptoms present on t O</b> <b>he last day the Subject</b> <b>Diary was completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E <b>Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:</b>	Initial Entry
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**2.b Symptom:**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Oct-02-2020 11:24:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> HEADACHE	New Information

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

			<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES Ongoing? NO Stop Date: Sep/20 20	
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**2.c Symptom:**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:24:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Sep/8/2020	New Information
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> C HI LL S <b>Were fever or systemic N</b> <b>symptoms present on t O</b> <b>he last day the Subject</b> <b>Diary was completed?:</b>	Initial Entry

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**2.d Symptom:**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> VO MI TIN G  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**2.e Symptom:**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> DI AR RH EA <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**2.f Symptom:**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENE MUSCL E PAIN  <b>Were fever or sys NO</b> <b>temic symptoms</b> <b>present on the las</b> <b>t day the Subject</b> <b>Diary was comple</b> <b>ted?:</b>	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levisse

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

2.g Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEW OR WORSENERED MU SCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> NEW O R WOR SENERED JOINT P AIN  <b>Were fever or syst NO</b> <b>emic symptoms p</b> <b>resent on the last</b> <b>day the Subject D</b> <b>iary was complete</b> <b>d?:</b>	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.lewissc

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

2.h Symptom:

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEW OR WORSENERD JOI NT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-02-2020 11:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-02-2020 11:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RIGHT	Transcription Error
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Injection Site Body Side entered on this page is not matching with Body Side entered on Vaccination page of V2VX2L. Please review and update as

090177e196ae26f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051069**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

				appropriate.
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> RE DN ES S  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW ELL ING	Initial Entry

**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History  
**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1005 **Site Name:** (1005) Rochester Clinical Research, Inc.  
**Subject No:** 10051069 **Subject Initials:** ---  
**Generated By:** pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

			Were injection site re NO actions present on the last day the Subject Diary was completed?:	
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**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-02-2020 11:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-02-2020 12:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-02-2020 12:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-02-2020 12:24:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-02-2020 12:24:19 (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-02-2020 12:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Date of Collection:  Oct/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2f6\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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Oct-02-2020 12:24:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BJ3W4N	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-02-2020 12:24:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BJ3W4N	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-02-2020 12:25:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BJ3W4P	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-02-2020 12:25:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BJ3W4P	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-02-2020 12:28:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BP9ZXN	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-02-2020 12:28:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BP9ZXN	Initial Entry

090177e196ae2f6f\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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.d**

Date	Location	User	Value	Reason
Oct-02-2020 12:28:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BP9ZXP	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-02-2020 12:28:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BP9ZXP	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Oct-02-2020 12:29:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BP9ZXR	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Oct-02-2020 12:29:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BP9ZXR	Initial Entry

090177e196ae2f6f\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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

Date	Location	User	Value	Reason
Oct-02-2020 11:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Oct/2/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-02-2020 11:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-02-2020 11:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae2f6f\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:** 10051069

**Generated By:** pfe.leviscc

**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

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Date	Location	User	Value	Reason
Sep-22-2020 09:45:13 (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:** 10051069

**Generated By:** pfe.lewissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-25-2020 23:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Clo sed	Response satisfies query
Nov-25-2020 22:58:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Clo sed	Response satisfies query
Nov-25-2020 17:07:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: An swere d	SAE form emailed
Nov-25-2020 17:07:09	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 3: An	When records are received

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

(UTC-05:00) Eastern Time (US & Canada)			swere d	will update SAE form
Nov-25-2020 01:37:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Op ened	CLINICAL - Please submit any SAE treatment followup including surgery.
Nov-25-2020 01:36:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Op ened	Clinical Please submit a SAE (#2020366988) safety update with the past med Hx of HTN, reported in the SAE med Hx section.
Sep-23-2020 10:09:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (pfe.weavee01)	Query 1: Clo sed	Response satisfies query
Sep-23-2020 07:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: An swere d	the medical history term has an end date. this is new
Sep-23-2020 04:11:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Op ened	The AE LEFT BREAST CANCER was reported but is also listed in Medical History. Please

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1005**Subject No:** 10051069**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

				clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. "[naikp09 SDQ=11045]"
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry</b> : LEFT BRE AST CAN CER	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-24-2020 04:53:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	onset date updated in both database. issue resolved
Sep-23-2020 13:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per mammogram medical records
Sep-23-2020 13:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Sep/4/2020 UNK:UNK	updated per mammogram medical records
Sep-23-2020 05:16:03 (UTC-05:00) Eastern	ACV0PFEINFP6000	Ricell Ann Piojo	Query 1: Opened	SAE RECON: AER#2020366988



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

Time (US & Canada)		(pfe.quitor)		
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Sep/1/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-10-2021 14:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> NO End Date Time:  Jan/12/2021 00:00	New Information
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-12-2021 13:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (pfe.liaukf)	Query 1: Closed	Response satisfies query
Mar-12-2021 10:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-12-2021 10:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> 2	New Information
Mar-10-2021 11:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (pfe.liaukf)	Query 1: Opened	GPD CLIN: AE of left breast cancer is considered serious; however, toxicity grade is 1. Please refer to protocol and update grade if applicable.

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Site No: 1005

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Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 1	Initial Entry
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**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

Date	Location	User	Value	Reason
Oct-22-2020 22:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	error
Oct-22-2020 22:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL - COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [# 2020366988] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Sep-23-2020 05:14:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-23-2020 02:43:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	For AE LEFT BREAST CANCER: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event

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**Header Text:** c4591001

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**Generated By:** pfe.levisse

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				Number" is blank.
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE LEFT BREAST CANCER: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Is this serious event associ ated with congenital anom aly or birth defect?  NO  Did this serious event resul t in death?  NO  Did this serious event requ ire or prolong hospitalizati on?  NO  Did this serious event resul t in persistent or significan t disability/incapacity?  NO  Is this serious event life thr eatening?  NO  Other medically important serious event	Initial Entry

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YES

**8. Is this adverse event the result of a study Medication Error?***If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT RELATED If Not Related to study treat ment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  PRE-EXISTING OCC ULT MALIGNANCY	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-12-2021 10:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> YES	Transcription Error
Jan-22-2021 06:13:07 (UTC-05:00) Eastern	ACV0PFEINFP6000	Daria Madar Jacobson	Query 1: Closed	Response satisfies query

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**Subject No:** 10051069

**Generated By:** pfe.levissc

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Time (US & Canada)		(pfe.madard)		
Jan-21-2021 14:22:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	confirmed
Jan-13-2021 08:17:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Please confirm that when enrolled to the study, subject met inclusion criterion #3 and was not receiving a prohibited systemic immunosuppressive therapy (see exclusion Criteria #8 and #13).
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-12-2021 11:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Mar-12-2021 10:17:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Query 1: Answered	updated Con Med answer to yes since subject takes Letrazole for her Left Breast Cancer. 2.5mg daily
Mar-07-2021 16:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: NON DRUG and Concomitant drug are listed both as NO. Please clarify if subject had a surgery and

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**Subject No:** 10051069

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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				whether she received a concomitant therapy. If yes, please specify and update CRF and SAE Fu report. Else, please clarify.
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Mar-12-2021 10:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-12-2021 10:13:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	<b>Data Entry:</b> RECOVERED/RESOLVE D	Transcription Error
Mar-10-2021 14:32:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE LEFT BREAST CANCER: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Oct-05-2020 15:42:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-05-2020 12:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	Subject in for V3-per subject she met with surgeon and discussed

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**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1005  
**Subject No:** 10051069  
**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Not Complete  
**Site Name:** (1005) Rochester Clinical Research, Inc.  
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				lumpectomy vs. mastectomy. Surgeon is waiting for more records from previous lumpectomy to determine which surgery to perform. Subject to f/u with site once surgery is performed and complete
Oct-02-2020 13:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL SAE narrative states surgical treatment plan for SAE to be determined at 30 Sep 2020 appointment. If safety update is available, please submit a follow-up form.
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 09:45:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Subject No:** 10051069

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

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*15. Serious Adverse Event Number: For Pfizer Use Only*

Date	Location	User	Value	Reason
Sep-23-2020 05:14:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2020366988	Initial Entry



**Header Text:** c4591001

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

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-01-2021 08:43:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nothando Magagula (pfe.magagn)	Query 1: Closed	Response satisfies query
Feb-01-2021 07:12:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-01-2021 07:12:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/13/2021	Transcription Error
Jan-31-2021 13:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nothando Magagula (pfe.magagn)	Query 1: Opened	Date of visit in Inform is 18 Jan 2021 however source and form 1 indicates contact was made on 13 Jan 2021.
Jan-19-2021 07:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.levissc

**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

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

Date	Location	User	Value	Reason
Jan-19-2021 07:49:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

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**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-19-2021 07:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-19-2021 07:49:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.lewissc

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

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

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-19-2021 07:50:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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***1. Consent Was:***

Date	Location	User	Value	Reason
Jan-19-2021 07:50:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/18/2021	Initial Entry

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**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER  
VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

Date	Location	User	Value	Reason
Jan-19-2021 07:51:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-19-2021 07:51:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-19-2021 07:51:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> COMPLETED	Initial Entry

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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 14-Jan-2021 02:21

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-19-2021 07:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-19-2021 07:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-19-2021 07:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-19-2021 07:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-19-2021 07:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jan-19-2021 07:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> 113 : <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-19-2021 07:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Jan-19-2021 07:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Jan-19-2021 07:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**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
Jan-19-2021 07:52:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-19-2021 07:52:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-19-2021 07:53:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 07:52:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 07:52:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Date of Collection:  Jan/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levissc

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

Jan-19-2021 07:53:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID: BRL2SM</b>	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 07:53:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BRL2SM	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-19-2021 07:53:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID: BRL2SN</b>	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 07:53:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BRL2SN	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-19-2021 07:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID: BRL2SP</b>	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 07:53:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BRL2SP	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.d**

Date	Location	User	Value	Reason
Jan-19-2021 07:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BS32XH	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 07:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BS32XH	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Jan-19-2021 07:54:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BS32XJ	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 07:54:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BS32XJ	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-19-2021 07:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-19-2021 07:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-19-2021 07:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 07:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 07:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Date of Collection:  Jan/18/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Jan-19-2021 07:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BRF81R	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 07:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BRF81R	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051069

Generated By: pfe.levissc

Form: VACCINATION - 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

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

Date	Location	User	Value	Reason
Jan-19-2021 07:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-19-2021 07:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-19-2021 07:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-19-2021 07:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/18/2021 14:49	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-19-2021 07:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051069

Generated By: pfe.levisse

Form: VACCINATION - 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

Jan-19-2021 07:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RIGHT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Jan-19-2021 07:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-19-2021 07:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-19-2021 07:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-19-2021 07:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-19-2021 07:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1005

**Subject No:** 10051069

**Generated By:** pfe.lewissc

**Form:** DATE OF VISIT - 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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-09-2021 07:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Feb/8/2021	Initial Entry



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Form Version:** 14-Jan-2021 02:21

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-09-2021 07:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-09-2021 07:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-09-2021 07:48:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-09-2021 07:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of collection is reported, but result is missing. Please review and update as appropriate.
Feb-09-2021 07:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Feb/8/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-09-2021 07:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1005

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

Subject No: 10051069

Subject Initials: ---

Generated By: pfe.levissc

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

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-09-2021 07:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-09-2021 07:48:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def ined Identifier:</b> <b>Test::</b> Choriogonado tropin Beta_P X113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry
Feb-09-2021 07:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sponsor-Def ined Identifier:</b> <b>Test::</b> Choriogonado tropin Beta_P X113 <b>Result::</b> <b>Not Done::</b>	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-09-2021 07:48:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
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090177e196ae26f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Form Version:** 14-Jan-2021 02:21

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Feb-09-2021 07:46:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Choriogonadotropin Beta_P X113	Initial Entry
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**6.a Not Done:**

Date	Location	User	Value	Reason
Feb-09-2021 07:48:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT DONE	Initial Entry

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Feb-09-2021 07:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-09-2021 07:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-15-2021 05:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-09-2021 15:32:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jennifer Riddle (pfe riddlj)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 07:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-09-2021 07:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f6f\Final\Final On: 01-Apr-2021 03:43 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

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

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

**Site No:** 1005

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

**Subject No:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Time (US & Canada)		(pfe.clomonaco)	Date of Collection:	
			Feb/8/2021	

**5.a**

Date	Location	User	Value	Reason
Feb-15-2021 05:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BRN01N	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-15-2021 05:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BRN01N	Initial Entry

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051069

Generated By: pfe.levissc

Form: VACCINATION - 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

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

Date	Location	User	Value	Reason
Feb-09-2021 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-09-2021 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-09-2021 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-09-2021 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Feb/8/2021 15:38	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-09-2021 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051069

Generated By: pfe.levisse

Form: VACCINATION - 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

Feb-09-2021 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RIGHT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Feb-09-2021 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-09-2021 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-09-2021 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-09-2021 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 07:48:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae26f\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:** 10051069

**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

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-02-2020 11:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-14-2020 09:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-14-2020 08:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-02-2020 11:24:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/2/2020	Initial Entry
Aug-14-2020 09:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/14/2020	Initial Entry
Aug-14-2020 08:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/14/2020	Initial Entry

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail 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:** 10051069

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Sep-10-2020 09:26:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae2f6\Final\Final On: 01-Apr-2021 03:43 (GMT)