

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

**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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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	01 DEC 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** MAIN INFORMED CONSENT

**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**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/10/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** DEMOGRAPHY

**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](#)

**Demography**

1.	Subject ID	[10051411]
2.	Birth Date:	(b) (6)/2003
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:** 10051411

**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/8/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.lewissc

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, 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
----	--	----------------

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** DISPOSITION - SCREENING

**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](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Jan/8/2021
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:** 10051411

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY

**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**

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[short bowel syndrome]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cholecystectomy]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[appendectomy]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[IMPERFORATE ANUS]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, 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:	[VOLVULUS]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RESECTION OF NECROTIC BOWEL]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003

1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSTOMY REVERSAL]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003

1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[INTESTINAL STOMA]
	Start Date:	UNK/UNK/2003
	Ongoing:	NO End Date: UNK/UNK/2003

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**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CONSTIPATION]
	Start Date:	UNK/UNK/2013
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** HIV STATUS

**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](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - BASELINE

**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](#)

**Vital Signs**

1.	Date:	Jan/8/2021
2.	Weight:	[101.4]
3.	Unit:	LB
4.	Height:	[63.0]
5.	Unit:	in
6.	Body Mass Index:	[18.0]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/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:	NEGATIVE
	Not Done:	

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**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** RANDOMIZATION

**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](#)

**Disposition**

1.	Randomization Date :	Jan/8/2021
2.	Randomization Number:	[117970]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.lewissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/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	[BR625P]
5.b	Sample ID	[BR625R]
5.c	Sample ID	[BR625S]
5.d	Sample ID	[BSMXGL]
5.e	Sample ID	[BSMXGM]

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**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**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: Jan/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	[BRGW59]
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090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**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?	YES Date of First Delay: Dec/10/2020  Reason(s) for Temporary Delay of Vaccination RECENT NON-STUDY VACCINATION
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/8/2021 11:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** REACTOGENICITY DIARY

**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](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051411

**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/28/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**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:** 10051411

**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
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP

**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](#)

**Vital Signs**

1.	Date:	Jan/28/2021
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.lewissc

**Form:** LAB URINALYSIS - PREGNANCY TEST

**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](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/28/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051411

**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: Jan/28/2021
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	[BRF83B]
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090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**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	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/28/2021 11:38
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** c4591001

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

**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:** 10051411

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

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	
2.	Symptom:	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	
3.	Injection Site Location:	
4.	Injection Site Body Side:	
5.	Injection Site Reaction:	
	Were injection site reactions present on the last day the Subject Diary was completed?	

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**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	[ ]
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090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1005

**Subject No:** 10051411

**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	[ ]
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**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1005

**Subject No:** 10051411

**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	[ ]
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090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1005

**Subject No:** 10051411

**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	[ ]
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090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**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 Visit

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

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

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

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

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**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?	
----	--	--

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**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:** 10051411

**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:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**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	[ ]
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**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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED						<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	ABDOMINAL PAIN	Jan/29/2021 UNK:UNK	NO End Date Time:  Feb/1/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Incomplete, Data Complete, Deleted

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

**Subject Initials:** ---

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

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

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

**Adverse Event Report**

1.	Category:	
2.	AE ID:	[ ]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ ]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
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).	
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.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Incomplete, Data Complete, Deleted

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

**Subject Initials:** ---

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

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

12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	
14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ABDOMINAL PAIN]
4.	Start Date Time:	Jan/29/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/1/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**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: [CONSTIPATION]
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	[2021117381]

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**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	[ ]

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	TETANUS VACCINE	Dec/4/2020	<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:** Data Complete, Frozen, Verified

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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[Form Audit Trail](#)

**Concomitant Medications**

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

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**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?	

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**Radiation Treatment**

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



**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

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

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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

**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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Unplanned Assessments**

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

**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:** 10051411

**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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vaccination**

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

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** 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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** End of Treatment - 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:** 10051411

**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:** 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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**eCRF Audit Trail History**

**Date of Visit**

1.	Date of Visit	Feb/3/2021
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:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 10-Dec-2020 02:27

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**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 :	Feb/3/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.lewissc

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Queries, 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	ENROLLED/RANDOMIZED
2.	Subject Status Date	Jan/8/2021

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Casebook Signature Form**

1.	Casebook Signature	
----	--------------------	--

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

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

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

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

**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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Item	Date	User	Comment
Form	Jan-11-2021 06:41:49 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Not Applicable

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

- CRF\_Sign
- CRF\_Sign\_1

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

**Visit:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** COHORT SELECTION - 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. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Dec-11-2020 06:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 01 DEC 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-11-2020 06:43:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** MAIN INFORMED CONSENT - 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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**I. Consent Was:**

Date	Location	User	Value	Reason
Jan-28-2021 04:09:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Jan-27-2021 09:01:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	Changed data per query
Jan-22-2021 00:59:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Reissued:Opened	DM1: Thank you for response. Per response 'subject met temporary delay criteria....' please update response to 'Was there a temporary delay of vaccination' as Yes and corresponding details on 'VACIN TRT' form at Visit 1. Else clarify.
Jan-21-2021 15:34:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	subject met temporary delay criteria on 10/DEC/2020 and came back on 08/JAN/2021 to complete Visit 1
Jan-14-2021 23:28:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Reissued:Opened	DM : Date Informed Consent Obtained (10/Dec /2020) is not same as Date of Visit (8/Jan/2021). Please review and update the data as appropriate. Else, clarify.

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**Form:** MAIN INFORMED CONSENT - 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-13-2021 11:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	correct as is as subject came back for visit
Jan-12-2021 06:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Dec-11-2020 06:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtain ed  Dec/10/2020	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: DEMOGRAPHY - 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. Subject ID**

Date	Location	User	Value	Reason
Dec-11-2020 06:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10051411	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Dec-11-2020 06:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/2003	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Dec-11-2020 06:43:51 (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
Dec-11-2020 06:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT HISPANIC OR LATINO( A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-11-2020 06:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**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
Jan-12-2021 06:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/8/2021	Transcription Error
Dec-11-2020 06:44:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Dec/10/2020	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:52

Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - 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 Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Jan-11-2021 06:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/8/2021	New Information
Dec-11-2020 06:44:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Dec/10/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-11-2020 06:44:25 (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
Jan-19-2021 03:34:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ananta Gogoi (pfe.gogoia)	Query 1: Closed	Response satisfies query
Jan-13-2021 01:11:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 2: Closed	Response satisfies query
Jan-12-2021 06:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 2: Answered	RAND FORM ADDED
Jan-11-2021 23:29:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 2: Reissued:Opened	IVRS Reconciliation RQ1: Randomization date and randomization number is recorded at impala but not recorded on RAND form under this visit. Please verify and update data as

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 15-Sep-2020 21:52**Site No:** 1005**Subject No:** 10051411**Generated By:** pfe.levisse**Form:** DISPOSITION - SCREENING - 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

				appropriate. Else clarify in query response.
Jan-11-2021 06:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 2: Answered	data added per source. please unfreeze dov form
Jan-11-2021 06:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 2: Opened	IVRS Reconciliation: Randomization date and randomization number recorded at impala but not recorded at inform. Please review and update data as appropriate. Else, clarify. Thank you.
Dec-30-2020 04:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 1: Reissued:Candidate	Need to be tracked post 08JAN2020.
Dec-28-2020 09:39:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	Subject met delay criteria, will return on 08JAN2020 to complete visit
Dec-14-2020 04:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Kindly consider updating all the missing pages under this visit. Thank you.
Dec-11-2020 06:44:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051411

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - 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.a*

Date	Location	User	Value	Reason
Jan-11-2021 06:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History</b> short bowel syn <b>Term:</b> drome <b>Start Date:</b> UNK/UNK/200 3 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Jan-11-2021 06:43:10 (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
Mar-12-2021 12:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Mar-11-2021 16:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	UPDATED
Mar-03-2021 10:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - Med hx unfrozen; please update with Constipation history
Jan-11-2021 06:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> short bowel syndrome	Initial Entry

*1.a Start Date:*

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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

Date	Location	User	Value	Reason
Jan-11-2021 06:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

***1.a Ongoing:***

Date	Location	User	Value	Reason
Jan-11-2021 06:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

***1.b***

Date	Location	User	Value	Reason
Jan-11-2021 06:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> cholecystectomy <b>Start Date:</b> UNK/UNK/2003 <b>Ongoing:</b> NO End Date: UNK/UNK/ 2003	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

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

Date	Location	User	Value	Reason
Jan-11-2021 06:43:30 (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
Jan-11-2021 06:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> cholecystectomy	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 06:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Jan-11-2021 06:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2003	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Jan-11-2021 06:43:51 (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> appendectomy <b>Start Date:</b> UNK/UNK/2003	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

			Ongoing:	NO End Date:  UNK/UNK/ 2003	
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**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Jan-11-2021 06:43:51 (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
Jan-11-2021 06:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> appendectomy	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Jan-11-2021 06:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Jan-11-2021 06:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2003	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Feb-09-2021 07:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num 4</b> <b>ber:</b>	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

			<b>Medical History Term:</b> IMPERFORATE ANUS <b>Start Date:</b> UNK/UNK/2003 <b>Ongoing:</b> NO End Date: UNK/UNK/2003	
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**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Feb-09-2021 07:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 07:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> IMPERFORATE ANUS	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Feb-09-2021 07:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Feb-09-2021 07:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO End Date: UNK/UNK/2003	Initial Entry

**I.e**

Date	Location	User	Value	Reason
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090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

Feb-09-2021 07:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> VOLVULUS <b>Start Date:</b> UNK/UNK/2003 <b>Ongoing:</b> NO End Date:  UNK/UNK/ 2003	Initial Entry
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*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Feb-09-2021 07:42:39 (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
Feb-09-2021 07:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> VOLVULUS	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Feb-09-2021 07:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Feb-09-2021 07:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2003	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY - 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

*I.f*

Date	Location	User	Value	Reason
Feb-16-2021 13:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> <b>Line/MH</b> 6 <b>Number:</b> <b>Medical H</b> RESECTION OF <b>istory Ter</b> NECROTIC BOW <b>m:</b> EL <b>Start Date</b> UNK/UNK/2003 <b>:</b> <b>Ongoing:</b> NO End Date: UNK/UNK/2003	Changed Information
Feb-09-2021 07:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/M</b> 6 <b>H Numb</b> <b>er:</b> <b>Medical</b> RESECTION OF NE <b>History</b> CROTIC BOWEL W <b>Term:</b> ITH OSTOMY <b>Start Da</b> UNK/UNK/2003 <b>te:</b> <b>Ongoing</b> NO <b>:</b> End Date: UNK/UNK/2003	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)



Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

*1.f Line/MH Number:*

Date	Location	User	Value	Reason
Feb-09-2021 07:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021 18:06:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Feb-16-2021 15:48:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Feb-16-2021 13:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Feb-16-2021 13:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-16-2021 13:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> RESECTION OF NECROTIC BOWEL	Changed Information
Feb-09-2021 11:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical - please note, do not add any current SAE information (including surgical path) in

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1005**Subject No:** 10051411**Generated By:** pfe.levissc**Form:** GENERAL MEDICAL HISTORY - 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

				this Past med hx location
Feb-09-2021 11:22:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	rewording
Feb-09-2021 11:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL SAE report (#2021117381) reports this surgery was required due to VOLVULUS- if concur, please update past Med Hx term with 'due to Volvulus' at the end.
Feb-09-2021 10:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Multiple concepts in the term RESECTION OF NECROTIC BOWEL WITH OSTOMY. Split the term into RESECTION OF NECROTIC BOWEL and INTESTINAL STOMA and submit separately. Thank you.
Feb-09-2021 07:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> RESECTION OF NECROTIC BOWEL WITH OSTOMY	Initial Entry

*I.f Start Date:*

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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

Date	Location	User	Value	Reason
Feb-09-2021 07:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

*If Ongoing:*

Date	Location	User	Value	Reason
Feb-09-2021 07:43:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2003	Initial Entry

*I.g*

Date	Location	User	Value	Reason
Feb-09-2021 07:43:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> OSTOMY REV ERSAL <b>Start Date:</b> UNK/UNK/2003 <b>Ongoing:</b> NO End Date:  UNK/UNK/2003	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

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

Date	Location	User	Value	Reason
Feb-09-2021 07:43:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Feb-09-2021 07:43:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> OSTOMY REVERSAL	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Feb-09-2021 07:43:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Feb-09-2021 07:43:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2003	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Feb-16-2021 13:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 8 <b>ber:</b> <b>Medical Histor</b> INTESTINAL S <b>y Term:</b> TOMA <b>Start Date:</b> UNK/UNK/2003	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**Form:** GENERAL MEDICAL HISTORY - 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

			<b>Ongoing:</b>	NO	
				End Date:	
				UNK/UNK/2	
				003	

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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.h Line/MH Number:**

Date	Location	User	Value	Reason
Feb-16-2021 13:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021 13:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> INTESTINAL STOMA	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Feb-16-2021 13:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> UNK/UNK/2003	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Feb-16-2021 13:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2003	Initial Entry

**1.i**

Date	Location	User	Value	Reason
Mar-11-2021 16:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 9 : <b>Medical History Term:</b> CONSTIPATI ON <b>Start Date:</b> UNK/UNK/2 013 <b>Ongoing:</b> YES	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.lewissc

**Form:** GENERAL MEDICAL HISTORY - 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

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

Date	Location	User	Value	Reason
Mar-11-2021 16:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Mar-11-2021 16:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> CONSTIPATION	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Mar-11-2021 16:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Mar-11-2021 16:58:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** HIV STATUS - 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. Select appropriate response - What is the subject HIV status?*

Date	Location	User	Value	Reason
Jan-11-2021 06:43:59 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> The subject is NOT known to b e HIV POSITIVE	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Dec-2020 02:29

Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - 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:**

Date	Location	User	Value	Reason
Jan-11-2021 06:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/8/2021	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Jan-11-2021 06:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 101.4	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Jan-11-2021 06:44:29 (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
Jan-11-2021 06:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 63.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Jan-11-2021 06:44:29 (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
Jan-11-2021 06:44:29 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 18.0	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Dec-2020 02:29

Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - 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

Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Jan-11-2021 06:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Record Identifier 1</b> :: <b>Temperature: 97.7</b> <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jan-11-2021 06:44:29 (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
Jan-11-2021 06:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 97.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jan-11-2021 06:44:29 (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
Jan-11-2021 06:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1005

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

Subject No: 10051411

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-11-2021 06:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-11-2021 06:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-11-2021 06:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Jan/8/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-11-2021 06:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-11-2021 06:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 10-Dec-2020 02:23

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

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Jan-11-2021 06:44:40 (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> NEGATIVE <b>Not Done::</b>	Initial Entry
--	-----------------	-------------------------	--	---------------

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-11-2021 06:44:40 (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-11-2021 06:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-11-2021 06:44:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051411

Generated By: pfe.levissc

Form: RANDOMIZATION - 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. Randomization Date :**

Date	Location	User	Value	Reason
Jan-12-2021 06:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-12-2021 06:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/8/2021	Transcription Error
Jan-12-2021 06:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Randomization Date 10/Dec/2020 is before or more than 1 day after corresponding Date of Visit 08/Jan /2021. Please review and update as appropriate.
Jan-12-2021 06:56:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Dec/10/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Jan-12-2021 06:56:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 117970	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (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, Frozen, Verified

Site No: 1005

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

Subject No: 10051411

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-11-2021 06:49:09 (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-11-2021 06:49:09 (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-12-2021 10:16:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Clo sed	Auto closed by Validation Check: VC_BEETRK001_04
Jan-12-2021 06:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 2: An swere d	CORRECT AS IS
Jan-11-2021 10:24:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Op ened	DMW6794910;Date of Collection is earlier or more than 1 day after Date of Visit. Please clarify or correct.
Jan-11-2021 06:49:21 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Del eted	Close Auto Query

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (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, Frozen, Verified

Site No: 1005

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

Subject No: 10051411

Subject Initials: ---

Generated By: pfe.levissc

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

(US & Canada)				
Jan-11-2021 06:49:09 (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-11-2021 06:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry</b> : YES Date of Collection:  Jan /8/ 20 21	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 06:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BR625P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 06:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BR625P	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-11-2021 06:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BR625R	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (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, Frozen, Verified

Site No: 1005

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

Subject No: 10051411

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 06:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> BR625R	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-11-2021 06:49:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Sample ID: BR625S	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 06:49:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> BR625S	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-11-2021 06:49:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Sample ID: BSMXGL	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 06:49:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> BSMXGL	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-11-2021 06:49:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Sample ID: BSMXGM	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

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

**5.e Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 06:49:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BSMXGM	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (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, Frozen, Verified

Site No: 1005

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

Subject No: 10051411

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-11-2021 06:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-11-2021 06:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-13-2021 02:45:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Jan-12-2021 06:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Jan-11-2021 16:48:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Reissued:Opened	DOV is unfrozen.
Jan-11-2021 06:51:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	please unfreeze dov form
Jan-11-2021 06:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-11-2021 06:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (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, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051411**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

				review and correct as appropriate.
Jan-11-2021 06:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection 08/Jan/2021 is more than 1 day after Date of Visit 10/Dec/2020. Please review and update as appropriate, else clarify.
Jan-11-2021 06:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Date of Collection:  Jan/8/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-11-2021 06:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Sample ID:</b> BRGW59	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-11-2021 06:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BRGW59	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051411

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-27-2021 09:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> YES Date of First Delay:  Dec/10/2020  Reason(s) for Temporary Del ay of Vaccination  RECENT NON-STUDY V ACCINATION	Transcription Error
Jan-11-2021 06:52:28 (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-11-2021 06:52:28 (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
Jan-11-2021 06:52:28 (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-13-2021 01:43:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 1: Closed	Response satisfies query
Jan-12-2021 06:57:22 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051411

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

Time (US & Canada)				
Jan-11-2021 23:45:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Reissued:Opened	DM: Thank you for the response. Form is not frozen kindly consider updating data as appropriate.
Jan-11-2021 06:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	PLEASE UNFREEZE DOV FORM
Jan-11-2021 06:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date is before or more than 1 day after Date of Visit 10/Dec/2020 of the corresponding Visit. Please review and update as appropriate.
Jan-11-2021 06:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/8/2021 11:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-11-2021 06:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-11-2021 06:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-11-2021 06:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-11-2021 06:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION 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
Jan-11-2021 06:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** REACTOGENICITY DIARY - 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. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Jan-11-2021 06:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES - REACTOGENICITY E- DIARY COLLECTED FOR T HIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**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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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-12-2021 11:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Mar-12-2021 10:25:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Query 1: Answered	Subject has yet to complete visit 3
Mar-09-2021 08:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: V3 has not been reported yet timepoint has passed - please clarify lack of V3 or update CRF with visit data. Please also review first EOT page that should be completed with date/status for end of phase (vax1/vax2/V3)
Jan-29-2021 06:48:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 10-Dec-2020 02:30**Site No:** 1005**Subject No:** 10051411**Generated By:** pfe.levissc**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM  
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  <b>Were fever or systemic sy N mptoms present on the la O st day the Subject Diary was completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> FA TI	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

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: 10051411

Subject Initials: ---

Generated By: pfe.levisse

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

			GU E NO	
<b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>				

**2.b Symptom:**

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (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>	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

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: 10051411

Subject Initials: ---

Generated By: pfe.levisse

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

2.c Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Symptom:: CH IL LS  Were fever or systemic s N ymptoms present on the l O ast day the Subject Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

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: 10051411

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic s NO ymptoms present on the last day the Subject Dia ry was completed?:</b>	Initial Entry

*2.e Symptom:*

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic s NO ymptoms present on the last day the Subject Dia ry was completed?:</b>	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

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: 10051411

Subject Initials: ---

Generated By: pfe.levisse

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

2.f Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

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: 10051411

Subject Initials: ---

Generated By: pfe.levisse

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

2.h

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENE D JOINT PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEW OR WORSENE D JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> LEFT	Initial Entry

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Header Text: c4591001

Visit: V2\_VAX2\_L

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

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: 10051411

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (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 react</b> NO <b>ions present on the last d</b> <b>ay the Subject Diary wa</b> <b>s completed?:</b>	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> SW : ELL ING <b>Were injection site reac</b> NO <b>tions present on the last</b> <b>day the Subject Diary w</b> <b>as completed?:</b>	Initial Entry

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Header Text: c4591001

Visit: V2\_VAX2\_L

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

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: 10051411

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-29-2021 06:49:17 (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
Jan-29-2021 06:49:17 (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: V2\_VAX2\_L

Form Version: 14-Jan-2021 02:22

Site No: 1005

Subject No: 10051411

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - 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:**

Date	Location	User	Value	Reason
Jan-29-2021 06:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-29-2021 06:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Record Identifier 1 :: Temperature: 97.4 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-29-2021 06:49:43 (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
Jan-29-2021 06:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 97.4	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Jan-29-2021 06:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> F	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 14-Jan-2021 02:22

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

**Form:** VITAL SIGNS - TEMP - 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

**2.a Temperature Location:**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-29-2021 06:49:43 (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: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1005

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

Subject No: 10051411

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-29-2021 06:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-29-2021 06:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-29-2021 06:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Jan/28/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-29-2021 06:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-29-2021 06:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Dec-2020 02:23

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

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Jan-29-2021 06:50:00 (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> NEGATIVE <b>Not Done::</b>	Initial Entry
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-29-2021 06:50:00 (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-29-2021 06:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-29-2021 06:50:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NEGATIVE	Initial Entry

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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, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051411**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-29-2021 06:50:10 (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-29-2021 06:50:10 (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-29-2021 06:50:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-29-2021 06:50:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-29-2021 06:50:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Date of Collection:  Jan/28/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-29-2021 06:50:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Sample ID: BRF83B	Initial Entry

**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, Frozen, Verified

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 06:50:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> BRF83B	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:26

Site No: 1005

Subject No: 10051411

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

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

Date	Location	User	Value	Reason
Jan-29-2021 06:50:49 (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-29-2021 06:50:49 (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
Jan-29-2021 06:50:49 (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-29-2021 06:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/28/2021 11:38	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-29-2021 06:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-29-2021 06:50:49 (UTC-05:00) Eastern	ACV0PFEINFP6000	Chelsey LoMonaco	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1005

**Subject No:** 10051411

**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

Time (US & Canada)		(pfe.clomonaco)	
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**7. Route:**

Date	Location	User	Value	Reason
Jan-29-2021 06:50:49 (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
Jan-29-2021 06:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION 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
Jan-29-2021 06:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

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

**Form Status:**

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**Subject Initials:** ---

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Date	Location	User	Value	Reason
Jan-21-2021 15:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Form Deleted	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levisse

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Date	Location	User	Value	Reason
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1005

Subject No: 10051411

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Data Complete, Deleted

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

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**1. Category:**

Date	Location	User	Value	Reason
Jan-21-2021 15:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-21-2021 15:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Jan-21-2021 15:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u>	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> PAIN AT INJECTION SITE	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-22-2021 01:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1005**Subject No:** 10051411**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Incomplete, Data Complete, Deleted**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

Jan-21-2021 15:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Transcription Error
Jan-21-2021 15:55:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	this AE was inadvertently entered on the wrong subject - unable to delete entry
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For PAIN AT INJECTION SITE: Start date 22/Dec/2020 is before VID1VX1L visit date 08/Jan /2021. Please review and update as appropriate.
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Dec/22/2020 04:00	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 15:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO End Date Time:  Dec/24/2020 20:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-21-2021 15:56:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Transcription Error

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Jan-12-2021 07:04:33 (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
Jan-21-2021 15:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Jan-21-2021 15:56:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Transcription Error
Jan-12-2021 07:04:33 (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
Jan-21-2021 15:56:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b>	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RELATED	Initial Entry

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Generated By: pfe.levisse

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Form Status: Incomplete, Data Complete, Deleted

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Subject Initials: ---

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

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-21-2021 15:56:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u>	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-21-2021 15:56:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u>	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-21-2021 15:57:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u>	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 15:57:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u>	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

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**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Jan-21-2021 15:57:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u>	Transcription Error
Jan-12-2021 07:04:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

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Subject Initials: ---

Generated By: pfe.levisse

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**1. Category:**

Date	Location	User	Value	Reason
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

**3. Adverse Event:**

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

Date	Location	User	Value	Reason
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> ABDOMINAL PAIN	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-16-2021 18:13:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-16-2021 13:10:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-16-2021 13:10:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> Jan/29/2021 UNK:UNK	Changed Information
Feb-10-2021 05:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2021117381 ,onset date was recorded as 29Jan2021 in Safety

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				database however, recorded as 30Jan2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Jan/30/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO End Date Time:  Feb/1/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-16-2021 18:13:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Feb-16-2021 13:11:29 (UTC-05:00) Eastern	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	UPDATED SAE FORM

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1005**Subject No:** 10051411**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - 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

Time (US & Canada)				SUBMITTED ON 08FEB2021
Feb-10-2021 03:50:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 14:50:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021117381] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE ABDOMINAL PAIN: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> YES Is this serious event associate d with congenital anomaly or birth defect?  NO  Did this serious event result i n death?  NO  Did this serious event require or prolong hospitalization?	Initial Entry

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			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

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

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

Date	Location	User	Value	Reason
Feb-03-2021 15:19:34 (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
Mar-03-2021 10:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-23-2021 13:13:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	please unfreeze med hx to add constipation
Feb-08-2021 14:52:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Other cause for event Abdominal Pain is constipation. This is not a prior Med Hx condition; please review for

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Header Text: c4591001

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				clinical significance and if appropriate, report on AE CRF (occurs prior to Visit 3).
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  CONSTIPATION	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-03-2021 15:19:34 (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
Feb-16-2021 18:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-16-2021 13:13:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-16-2021 13:13:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> YES	Changed Information
Feb-08-2021 14:50:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - Con Med for event is NO; however, SAE report states subject started on Glycolax. Please review Con Med,

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**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

				and update as appropriate
Feb-03-2021 15:19:34 (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
Feb-03-2021 15:19:34 (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
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021 15:19:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-10-2021 03:50:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	<b>Data Entry:</b> 2021117381	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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Date	Location	User	Value	Reason
Jan-21-2021 15:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-21-2021 15:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Jan-21-2021 15:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Jan-21-2021 15:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Jan-21-2021 19:42:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teresa Vu (pfe.vut11)	Query 1: Closed	Response satisfies query
Jan-21-2021 15:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-21-2021 15:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<b>Data Entry:</b> TETANUS VACCINE	Initial Entry
Jan-21-2021 15:33:01 (UTC-05:00) Eastern	ACV0PFEINFP6000	Teresa Vu (pfe.vut11)	Query 1: Opened	per source, Subject received tetanus

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)

vaccine on  
4Dec2020. Please  
add to EDC.

**5. Date:**

Date	Location	User	Value	Reason
Jan-21-2021 15:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	<u>Data Entry:</u> Dec/4/2020	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:** 10051411

**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-04-2021 05:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Feb/3/2021	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1005

**Subject No:** 10051411

**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
Feb-04-2021 05:57:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Participant is willing to return f or Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placeb o at Vaccination 1/2	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Form Version:** 10-Dec-2020 02:27

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

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-04-2021 05:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> Feb/3/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-04-2021 05:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1005

**Subject No:** 10051411

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Queries, 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
Jan-12-2021 06:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Transcription Error
Jan-12-2021 06:56:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Dec-11-2020 06:44:25 (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
Mar-12-2021 15:22:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Behnaz Yousefzadeh- Khiabani (pfe.youseb01)	Query 2: Reissued:Opened	Please update once data is available.
Mar-12-2021 10:24:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Query 2: Answered	Patient has yet to complete Visit 3
Mar-09-2021 02:47:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Natasha Rajkumar (pfe.rajkun)	Query 2: Opened	DM: Visit 3 is overdue based on expected visit window. Please enter data or, if visit will never occur, mark Date of Visit as 'Not Done' with form level comment. If subject is no longer in the trial, complete the Disposition FUP and EOT form.
Feb-25-2021 12:32:38 (UTC-05:00) Eastern	ACV0PFEINFP6000	Ajit Malode (pfe.maloda)	Query 1: Closed	query closed based on site's

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

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

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

**Site No:** 1005

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

**Subject No:** 10051411

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

Time (US & Canada)				confirmation-erroneous entry.
Feb-24-2021 16:27:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 1: Answered	per subject's mother, subject inadvertently answered yes to covid symptoms.
Feb-24-2021 09:53:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 19FEB2021. But there is no COVID Illness visit reported in the database. Please clarify.
Jan-12-2021 06:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/8/2021	Transcription Error
Jan-12-2021 06:56:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/10/2020	Initial Entry
Jan-11-2021 06:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Jan/8/2021	New Information
Dec-11-2020 06:44:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/10/2020	Initial Entry

090177e196ae2f7e\Final\Final On: 01-Apr-2021 03:44 (GMT)