

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/13/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10051047]
2.	Birth Date:	(b) (6)/1949
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/13/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTENSION]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[gastroesophageal reflux disease]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[POST MENOPAUSAL]
	Start Date:	UNK/UNK/1997
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERLIPIDEMIA]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPOTHYROID]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES

090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[VITAMIN B12 DEFICIENCY]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[APPENDECTOMY]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1990
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ACUTE APPENDICITIS]
	Start Date:	UNK/UNK/1990
	Ongoing:	NO End Date: UNK/UNK/1990
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RIGHT ANKLE REPLACEMENT]
	Start Date:	UNK/UNK/2019
	Ongoing:	NO End Date: UNK/UNK/2019

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RIGHT ANKLE FRACTURE]
	Start Date:	UNK/UNK/2019
	Ongoing:	NO End Date: UNK/UNK/2019
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[TUBAL LIGATION]
	Start Date:	UNK/UNK/1975
	Ongoing:	NO End Date: UNK/UNK/1975
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HIATAL HERNIA]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/13/2020
2.	Weight:	[201.0]
3.	Unit:	LB
4.	Height:	[67.0]
5.	Unit:	in
6.	Body Mass Index:	[31.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/13/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/13/2020
2.	Randomization Number:	[227512]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BKNWD5]
5.b	Sample ID	[BKNWD7]
5.c	Sample ID	[BKNWD6]
5.d	Sample ID	[BLCZJY]
5.e	Sample ID	[BLCZJZ]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM8R25]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/13/2020 09:55
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

090177e196ae2f7\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: 10051047

Generated By: pfe.lewissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae2f7\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: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

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

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/1/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/1/2020 11:32
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

090177e196ae2f7\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: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae27f\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM5FHP]
5.b	Sample ID	[BM5FHN]
5.c	Sample ID	[BM5FHM]
5.d	Sample ID	[BJ3VZT]
5.e	Sample ID	[BJ3VZS]

090177e196ae2f7\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: 10051047

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	Mar/1/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

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: Mar/1/2021
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	[BRF8CL]
5.b	Sample ID	[BRF8CM]
5.c	Sample ID	[BRF8CN]
5.d	Sample ID	[BSC2WW]
5.e	Sample ID	[BSC2WX]

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051047

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: 10051047

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

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051047

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: 10051047

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

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: 10051047

Subject Initials: ---

Generated By: pfe.leviscc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1005

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

Subject No: 10051047

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: 10051047

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:** 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: 10051047

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?	
----	--	--

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: 10051047

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: 10051047

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: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1005

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

Subject No: 10051047

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: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Sep/29/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1005

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

Subject No: 10051047

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: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	AORTIC ANEURYSM	Nov/20/2020 UNK: UNK	NO End Date Time: Jan/28/2021 UNK:UNK	Repeating Pages

090177e196ae2f7\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: 10051047

Generated By: pfe.lewissc

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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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[AORTIC ANEURYSM]
4.	Start Date Time:	Nov/20/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/28/2021 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
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: [occult condition, pre-existing]

090177e196ae2f7\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: 10051047

Generated By: pfe.lewissc

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

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	[2021107068]

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: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae2f7\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: 10051047

Generated By: pfe.lewissc

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

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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	[]

090177e196ae2f7\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: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

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

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae2f7\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: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

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

090177e196ae2f7\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: 10051047

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae2f7\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: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae2f7f\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: 10051047

Generated By: pfe.lewissc

Form: RADIATION TREATMENT

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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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: 10051047

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae2f7f\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: 10051047

Generated By: pfe.lewissc

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1005

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

Subject No: 10051047

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: 10051047

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: 10051047

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:	

090177e196ae2f7\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: 10051047

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?	

090177e196ae2f7\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: 10051047

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: 10051047

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: 10051047

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: 10051047

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: 10051047

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: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

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/2/2021
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: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

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/2/2021
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: 10051047

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 :	//
----	------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

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: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/29/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Matthew Davis	Approved	Mar-09-2021 14:06:28 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-13-2020 09:57:04 (UTC-05:00) Eastern Time (US & Canada)	Chelsey LoMonaco (pfe.clomonaco)	Not Applicable

090177e196ae2f7\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: Data Complete, Signed, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Matthew Davis	Approved	Mar-09-2021 14:06:28 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Chelsey LoMonaco	N/A	Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Matthew Davis	Approved	Oct-01-2020 10:03:08 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Chelsey LoMonaco	N/A	Sep-29-2020 13:06:10 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Matthew Davis	Approved	Sep-10-2020 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae27f\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

Affidavit:

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

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

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

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-13-2020 09:56:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:56:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-13-2020 09:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: OBTAINED Date Written Consent Obtained Aug/13/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-13-2020 09:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10051047	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-13-2020 09:56:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1949	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-13-2020 09:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-13-2020 09:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: WHITE	Initial Entry

090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-17-2020 05:03:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Response satisfies query
Aug-14-2020 10:10:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Abigail Purcell (pfe.apurcell)	Query 1: Answered	DATA ADDED PER REQUEST
Aug-14-2020 06:50:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	DM Query: Kindly review and complete 'Reactogenicity form' at this visit. Thank you.
Aug-13-2020 09:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Aug/13/2020	Initial Entry

090177e196ae2f7\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: 10051047

Generated By: pfe.lewissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-13-2020 09:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Aug/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-13-2020 09:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-13-2020 09:57:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-13-2020 09:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: HYPERTENSION Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 09:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: HYPERTENSION	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 09:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/1990	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 09:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
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090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Aug-19-2020 06:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Line/MH Nu 2 mber: Medical Histo gastroesophageal r ry Term: eflux disease Start Date: UNK/UNK/2009 Ongoing: YES	Transcription Error
Aug-17-2020 10:44:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Line/MH Nu 2 mber: Medical Histo gastroesophageal r ry Term: eflux disease Start Date: UNK/UNK/2009 Ongoing: YES	Transcription Error
Aug-17-2020 08:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Line/MH Nu 2 mber: Medical Hist gastroesophogeal r ory Term: eflux disease Start Date: UNK/UNK/2009 Ongoing: YES	New Information
Aug-17-2020 06:24:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Line/MH Nu 2 mber: Medical Hist Gastroesophageal ory Term: reflux disease Start Date: UNK/UNK/2009 Ongoing: YES	Transcription Error
Aug-13-2020 09:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 2 mber: Medical Hist Gastroesophageal ory Term: reflux disease Start Date: UNK/UNK/2009 Ongoing: YES	Initial Entry

090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 09:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 09:42:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 2: Closed	Response satisfies query
Aug-20-2020 08:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Response satisfies query
Aug-20-2020 08:09:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 3: Closed	Response satisfies query
Aug-19-2020 06:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Aug-19-2020 06:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-19-2020 06:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: gastro esoph	Transcription Error

090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Canada)			ageal reflux disease	
Aug-18-2020 12:01:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 3: Opened	DM QUERY: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Aug-18-2020 08:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Reissued: Opened	Requery: There is still a trailing space at the end of the term. Please delete and re-enter the data (without using copy and paste) to remove the identified character.
Aug-17-2020 10:44:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Aug-17-2020 10:44:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry gastroesophageal reflux disease	Transcription Error
Aug-17-2020 09:50:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Clarify GASTROESOPHOGEAL REFLUX DISEASE as follows...Should the spelling be GASTROESOPHAGEAL REFLUX DISEASE? If so, edit. Otherwise clarify.Thank you.
Aug-17-2020	ACV0PFEINFP6000	auto query (autoquery)	Query	New Information

090177e196ae27f\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: 10051047

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

08:17:22 (UTC-05:00) Eastern Time (US & Canada)			1: Ans wered	
Aug-17-2020 08:17:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry : gastro esoph ogeal reflux diseas e	New Information
Aug-17-2020 06:51:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Rei ssued: Opene d	Requery: Please consider to delete the entry and re-enter the data (without using copy and paste) to remove the trailing space identified.
Aug-17-2020 06:24:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Aug-17-2020 06:24:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry : Gastr oesop hageal reflux diseas e	Transcription Error
Aug-14-2020 15:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 1: Op ened	DM QUERY: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Aug-13-2020	ACV0PFEINFP6000	Chelsey LoMonaco	Data	Initial Entry

090177e196ae27f\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

09:58:49 (UTC-05:00) Eastern Time (US & Canada)		(pfe.clomonaco)	Entry : Gastr oesop hageal reflux diseas e	
---	--	-----------------	--	--

I.b Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 09:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/2009	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 09:58:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Aug-13-2020 09:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 3 r: Medical History POST MENOPA Term: USAL Start Date: UNK/UNK/1997 Ongoing: YES	Initial Entry

090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: POST MENOPAUSAL	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/1997	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-13-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 4 : Medical History T HYPERLIPIDE erm: MIA Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: HYPERLIPIDEMIA	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/1990	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-13-2020 09:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: HYPOTHYROID Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

090177e196ae2f7\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: 10051047

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: HYPOTHYROID	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/1990	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-13-2020 09:59:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 6 ber: Medical Histor VITAMIN B12 DE y Term: FICIENCY Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

090177e196ae2f7\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: 10051047

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

If Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

If Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: VITAMIN B12 DEFICIENCY	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/2015	Initial Entry

090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

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I.f Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-13-2020 09:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History Term: APPENDECTO MY Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1 990	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: APPENDECTOMY	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/1990	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 09:59:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO End Date: UNK/UNK/1990	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-13-2020 10:00:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: ACUTE APPENDICITIS Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/1990	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

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Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

I.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 10:00:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 10:00:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: ACUTE APPENDICITIS	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 10:00:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/1990	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 10:00:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO End Date: UNK/UNK/1990	Initial Entry

I.i

Date	Location	User	Value	Reason
Aug-13-2020 10:01:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Line/MH N umber: 9 Medical His tory Term: RIGHT ANKLE R EPLACEMENT Start Date: UNK/UNK/2019 Ongoing: NO End Date: UNK/UNK/2019	Transcription Error
Aug-13-2020 10:00:32 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 9	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

Time (US & Canada)			Number: Medical History Term: ANKLE REPLACEMENT Start Date: UNK/UNK/2019 Ongoing: NO End Date: UNK/UNK/2019	
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I.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 10:00:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 10:01:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: RIGHT ANKLE REPLACEMENT	Transcription Error
Aug-13-2020 10:00:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: ANKLE REPLACEMENT	Initial Entry

I.i Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 10:00:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/2019	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 10:00:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry

I.j

Date	Location	User	Value	Reason
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090177e196ae2f7\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: 10051047

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Aug-13-2020 10:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 10 ber: Medical History Term: RIGHT ANKLE FRACTURE Start Date: UNK/UNK/2019 Ongoing: NO End Date: UNK/UNK/2019	Initial Entry
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I.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 10:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 10:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: RIGHT ANKLE FRACTURE	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 10:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/2019	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 10:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry

I.k

Date	Location	User	Value	Reason
Aug-13-2020 10:01:38 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae2f7\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: 10051047

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

(US & Canada)			Line/MH Number 11 : Medical History Term: TUBAL LIGATI ON Start Date: UNK/UNK/1975 Ongoing: NO End Date: UNK/UNK/1 975	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

I.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 10:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 19:06:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Closed	Response satisfies query
Aug-17-2020 06:25:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Query 1: Answered	THIS WAS DONE FOR PREGNANCY PREVENTION
Aug-16-2020 00:05:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Opened	TUBAL LIGATION : please also record the condition/disease that led to the surgery/procedure being required. Please review and update.
Aug-13-2020 10:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: TUBAL LIGATION	Initial Entry

I.k Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 10:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: UNK/UNK/1975	Initial Entry

I.k Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 10:01:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO End Date: UNK/UNK/1975	Initial Entry

I.l

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Feb-11-2021 18:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: HIATAL HERNIA Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Feb-11-2021 18:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Feb-11-2021 18:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Data Entry: HIATAL HERNIA	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Feb-11-2021 18:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Data Entry: UNK/UNK/1995	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Feb-11-2021 18:26:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Data Entry: YES	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Aug/13/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 201.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-13-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	lb is selected for weight unit, then in is expected to be selected for Height unit. Please check and update data as appropriate.
Aug-13-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-13-2020 10:02:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 67.0	Transcription Error
Aug-13-2020 10:02:11 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Height 667 is outside of Normal Range 140

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

Time (US & Canada)				- 198 for cm or 55 - 80 for in.
Aug-13-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 667.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: in	Transcription Error
Aug-13-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 31.5	Transcription Error
Aug-13-2020 10:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 0.3	Transcription Error
Aug-13-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-13-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Locat ion:: ORAL CAVI TY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:11	ACV0PFEINFP6000	Chelsey	Data Entry:	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)		LoMonaco (pfe.clomonaco)	1	
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7.a Temperature:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 97.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2f7\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

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
Aug-13-2020 10:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Aug/13/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-13-2020 10:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-13-2020 10:03:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sponsor-Defin 113 ed Identifier:	Transcription Error

090177e196ae2f7\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

			Test:: Choriogonadotro pin Beta_PX113 Result:: Not Done:: NOT DONE	
Aug-13-2020 10:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defin 113 ed Identifier: Test:: Choriogonadotro pin Beta_PX113 Result:: NEGATIVE Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-13-2020 10:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-13-2020 10:03:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry:	Transcription Error
Aug-13-2020 10:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NEGATIVE	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-13-2020 10:03:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Aug-13-2020 10:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Not Done is indicated however result is provided. Please correct or clarify.
Aug-13-2020 10:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT DONE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-13-2020 10:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Aug/13/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-13-2020 10:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 227512	Initial Entry

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
 Form Version: 22-Apr-2020 21:03
 Site No: 1005
 Subject No: 10051047
 Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
 eCRF Audit Trail History
 Form Status: Data Complete, Locked, Frozen, Verified
 Site Name: (1005) Rochester Clinical Research, Inc.
 Subject Initials: ---
 Generated Time (GMT): 29-Mar-2021 04:04

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1. Data Origin

Date	Location	User	Value	Reason
Aug-13-2020 10:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-13-2020 10:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-13-2020 10:03:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 10:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-13-2020 10:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES Date of Collection: Aug/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-13-2020 10:03:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BKNWD5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f7\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, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-13-2020 10:03:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BKNWD5	Initial Entry
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5.b

Date	Location	User	Value	Reason
Aug-13-2020 10:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BKNWD7	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 10:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BKNWD7	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-13-2020 10:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BKNWD6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 10:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BKNWD6	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-13-2020 10:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BLCZJY	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 10:04:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BLCZJY	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

5.e

Date	Location	User	Value	Reason
Aug-13-2020 10:04:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BLCZJZ	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 10:04:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BLCZJZ	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-13-2020 10:04:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-13-2020 10:04:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-13-2020 10:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 10:04:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-13-2020 10:04:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES Date of Collection: Aug/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-13-2020 10:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BM8R25	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Aug-13-2020 10:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BM8R25	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-13-2020 11:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-13-2020 11:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-13-2020 11:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-13-2020 11:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Aug/13/2020 09:55	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-13-2020 11:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-13-2020 11:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-13-2020 11:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-13-2020 11:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 11:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

090177e196ae2f7\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: 10051047

Generated By: pfe.lewissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-14-2020 10:10:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Abigail Purcell (pfe.apurcell)	Data Entry: YES - REACTOGENICITY E-DIAR Y COLLECTED FOR THIS SUBJE CT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 14:16:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: FE VE R Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: FA TIG UE	Initial Entry

090177e196ae2f7\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: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (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
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae27f\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: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

2.d

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: CH IL LS Were fever or systemic sym NO ptoms present on the last da y the Subject Diary was com pleted?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: VO MIT ING Were fever or systemic sym NO ptoms present on the last d ay the Subject Diary was c ompleted?:	Initial Entry

090177e196ae27f\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: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

2.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> <u>Symptom::</u> DIA RR HE A Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
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090177e196ae27f\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: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: NEW OR WORSE NED MUS CLE PAIN Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?: NO	Initial Entry
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2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NEW OR WORSE NED MUSC CLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or systemi c symptoms present o n the last day the Sub ject Diary was complet ed?: NO	Initial Entry

090177e196ae2f7\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: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

2.h Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NEW OR WORSENE D JOINT PA IN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Injection Site Reaction:: RE DN ESS Were injection site reaction NO s present on the last day the Subject Diary was complete d?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11	ACV0PFEINFP6000	Chelsey	<u>Data Entry:</u>	Initial Entry

090177e196ae2f7\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: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

(UTC-05:00) Eastern Time
(US & Canada)

LoMonaco
(pfe.clomonaco)

REDNESS

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE	Initial Entry

090177e196ae2f7\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: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

			Were injection site reactions present on the last day the Subject Diary was completed?:	NO
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/1/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 14:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Locat ORAL CAVI ion:: TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 14:17:57	ACV0PFEINFP6000	Chelsey	Data Entry:	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1005

Subject No: 10051047

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)		LoMonaco (pfe.clomonaco)	ORAL CAVITY	
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-01-2020 14:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-01-2020 14:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-01-2020 14:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/1/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-01-2020 14:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-01-2020 14:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-01-2020 14:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 113 d Identifier:	Initial Entry

090177e196ae2f7\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: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Sep-01-2020 14:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-01-2020 14:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-01-2020 14:18:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT DONE	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 14:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 14:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 14:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 14:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 14:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 14:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BKNVSW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Sep-01-2020 14:18:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BKNVSW	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-01-2020 14:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 14:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-01-2020 14:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-01-2020 14:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/1/2020 11:32	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 14:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 14:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-01-2020 14:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-01-2020 14:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 14:19:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-29-2020 13:06:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/29/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: FE VE R Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: FA TIG UE	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> Symptom:: HEA DA CHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (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
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae27f\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

2.d

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

2.e Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> <u>Symptom::</u> DIA RR HE A Were fever or systemic sym ptoms present on the last d ay the Subject Diary was co mpleted?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
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090177e196ae27f\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: NEW OR WORSE ED MUS CLE PAIN Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was compl eted?:	Initial Entry
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2.g Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 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
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Symptom:: NEW OR WORSE NED JOI NT PAIN Were fever or systemi NO c symptoms present o n the last day the Sub ject Diary was complet ed?:	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

2.h Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NEW OR WORSENERD JOINT PA IN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reaction NO s present on the last day the Subject Diary was complete d?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44	ACV0PFEINFP6000	Chelsey	Data Entry:	Initial Entry

090177e196ae27f\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1005**Site Name:** (1005) Rochester Clinical Research, Inc.**Subject No:** 10051047**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04(UTC-05:00) Eastern Time
(US & Canada)LoMonaco
(pfe.clomonaco)

REDNESS

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

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

			Were injection site reactions present on the last day the Subject Diary was completed?:	NO
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 13:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-29-2020 13:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-29-2020 13:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-29-2020 13:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 13:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-29-2020 13:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES Date of Collection: Sep/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 13:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BM5FHP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-29-2020 13:07:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BM5FHP	Initial Entry
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5.b

Date	Location	User	Value	Reason
Sep-29-2020 13:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BM5FHN	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 13:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BM5FHN	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 13:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BM5FHM	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 13:07:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BM5FHM	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-29-2020 13:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BJ3VZT	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 13:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BJ3VZT	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

5.e

Date	Location	User	Value	Reason
Sep-29-2020 13:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sample ID: BJ3VZS	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 13:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: BJ3VZS	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051047

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
Mar-02-2021 12:02:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: Mar/1/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_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: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-02-2021 12:02:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-02-2021 12:02:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-02-2021 12:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 12:02:28 (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.
Mar-02-2021 12:02:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: YES Date of Collection: Mar/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-02-2021 12:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: Sample ID: BRF8CL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_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: 10051047

Subject Initials: ---

Generated By: pfe.levisse

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

Mar-02-2021 12:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: BRF8CL	Initial Entry
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5.b

Date	Location	User	Value	Reason
Mar-02-2021 12:02:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: Sample ID: BRF8CM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 12:02:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: BRF8CM	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-02-2021 12:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: Sample ID: BRF8CN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 12:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: BRF8CN	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-02-2021 12:02:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: Sample ID: BSC2WW	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 12:02:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: BSC2WW	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Mar-02-2021 12:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: Sample ID: BSC2WX	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 12:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jessica Fisher (pfe.jfisher)	Data Entry: BSC2WX	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-29-2020 13:08:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Sep/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-29-2020 13:08:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-29-2020 13:08:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: COMPLETED	Initial Entry

090177e196ae2f7\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: 10051047

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Category:

Date	Location	User	Value	Reason
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: AORTIC ANEURYSM	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-15-2021 17:27:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-08-2021 11:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-08-2021 11:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Data Entry: Nov/20/2020 UNK:UNK	New Information
Feb-04-2021 01:04:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Event start date is 20Jan21; however, SAE reports that aneurysm was detected on routine ECHO in Nov20. In Vaccine study, SAE start date is day

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1005

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

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Subject Initials: ---

Generated By: pfe.levissc

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

				event starts; not day it meets serious criteria (item 11 in vaccine SAE instruct). Review start date
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Jan/20/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO End Date Time: Jan/28/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-15-2021 17:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Feb-08-2021 11:40:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Query 2: Answered	covid test completed pre-operatively prior to hospitalization. Updated SAE form to be submitted today.
Feb-05-2021 08:52:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

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

Feb-04-2021 01:02:31 (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 [#2021107068] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE AORTIC ANEURYSM: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: 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	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

			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-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-05-2021 01:41:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Adarsh Prabhu (pfe.prabha11)	Query 1: Closed	Response satisfies query
Feb-04-2021 07:26:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-04-2021 07:26:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Julie Mooney (pfe.jmooney)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: occult condition, pre-existing	Transcription Error
Feb-04-2021 01:48:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: If other is selected then please complete specify field. Thank you.
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.lewissc

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

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Feb-02-2021 20:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-05-2021 08:52:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Data Entry: 2021107068	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1005

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

Subject No: 10051047

Subject Initials: ---

Generated By: pfe.levissc

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-15-2021 13:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sharreda Cornes (pfe.cornes09)	Query 1: Closed	Response satisfies query
Feb-15-2021 05:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-15-2021 05:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Feb/2/2021	Initial Entry
Feb-14-2021 15:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Teresa Vu (pfe.vut11)	Query 1: Opened	Per source this visit was completed on 2Feb21, Form 1 subject was on vaccine at V1 and V2 and qualified to be unblinded by the protocol. Please confirm and complete data entry.

090177e196ae2f7\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: 10051047

Generated By: pfe.lewissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-15-2021 05:51:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Participant is willing to return for V accination 3 Participant is: eligible and NOT confirmed to h ave received only placebo at Vac cination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-15-2021 05:50:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Feb/2/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-15-2021 05:50:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: ASSESS ELIGIBILITY FOR ADD ITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Subject Status

Date	Location	User	Value	Reason
Sep-29-2020 13:08:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-13-2020 10:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-13-2020 09:57:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Sep-29-2020 13:08:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/29/2020	Initial Entry
Aug-13-2020 10:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/13/2020	Initial Entry
Aug-13-2020 09:57:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/13/2020	Initial Entry

090177e196ae2f7\Final\Final On: 01-Apr-2021 03:44 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1005

Subject No: 10051047

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

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

Subject Initials: ---

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-10-2020 09:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Chelsey LoMonaco (pfe.clomonaco)	Data Entry: Click Here to Enable	Initial Entry