

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jun-2020 00:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	27 MAY 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 1 SENTINEL COHORTS

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jun/12/2020
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Form Version: 22-Apr-2020 21:05

Site No: 1003

Subject No: 10031065

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Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10031065]
2.	Birth Date:	(b) (6)/1968
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:	

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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Date of Visit

1.	Date of Visit	Jun/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

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Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00
1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00
1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

Exclusion Criteria

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

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Subject No: 10031065

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Form: INCLUSION/EXCLUSION CRITERIA

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

2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	5
	Criterion Description:	Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX05A00
2.f	Exclusion Number:	6
	Criterion Description:	Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX06A01
2.g	Exclusion Number:	7
	Criterion Description:	Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX07A00

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Form Version: 06-Jun-2020 00:48

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2 h	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
2.i	Exclusion Number:	9
	Criterion Description:	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX09A00
2.j	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2 k	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2.l	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2 m	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Visit: SCR

Form Version: 06-Jun-2020 00:48

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Subject No: 10031065

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Form: INCLUSION/EXCLUSION CRITERIA

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

2 n	Exclusion Number:	14
	Criterion Description:	Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX22A01
2.o	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01
2.p	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.q	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2 r	Exclusion Number:	18
	Criterion Description:	Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX17A01
2.s	Exclusion Number:	19
	Criterion Description:	Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX18A01

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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

2.t	Exclusion Number:	20
	Criterion Description:	Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX19A01
2.u	Exclusion Number:	21
	Criterion Description:	Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX20A01
2.v	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Jun/12/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

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

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Medical History Details

1.a	Line/MH Number:	Not Applicable _____ []	Comments
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____ []	Comments
	Start Date:	Not Applicable _____ //	Comments
	Ongoing:	Not Applicable _____	Comments
1.b	Line/MH Number:	[2]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Wears Glasses]	
	Start Date:	UNK/UNK/1982	
	Ongoing:	YES	
1.c	Line/MH Number:	[3]	
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Deviated Septum - Nasal Surgery]	
	Start Date:	UNK/UNK/2010	
	Ongoing:	NO End Date: UNK/UNK/2010	

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE

Form Version: 22-Apr-2020 21:04

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
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).	Not Applicable _____ []	Comments
5.	Dose:	Not Applicable _____ []	Comments
6.	Dose Unit:	Not Applicable _____	Comments
7.	Dose Frequency:	Not Applicable _____	Comments
8.	Route:	Not Applicable _____	Comments
9.	Start Date:	Not Applicable _____ //	Comments

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION

Form Version: 06-Jun-2020 00:46

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jun/12/2020
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Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE
	Result:	NORMAL
2.b	Body System Examined:	SKIN
	Result:	NORMAL
2.c	Body System Examined:	HEAD
	Result:	NORMAL
2.d	Body System Examined:	EYES
	Result:	NORMAL
2.e	Body System Examined:	EARS
	Result:	NORMAL
2.f	Body System Examined:	NOSE
	Result:	NORMAL
2.g	Body System Examined:	THROAT
	Result:	NORMAL
2.h	Body System Examined:	HEART
	Result:	NORMAL
2.i	Body System Examined:	LUNGS
	Result:	NORMAL
2.j	Body System Examined:	ABDOMEN
	Result:	NORMAL
2.k	Body System Examined:	MUSCULOSKELETAL
	Result:	NORMAL

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:46

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.1	Body System Examined:	EXTREMITIES
	Result:	NORMAL
2 m	Body System Examined:	NEUROLOGICAL
	Result:	NORMAL
2 n	Body System Examined:	LYMPH NODES
	Result:	NORMAL

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: VITAL SIGNS - BASELINE

Form Version: 06-Jun-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jun/12/2020
2.	Weight:	[154.0]
3.	Unit:	LB
4.	Height:	[67.0]
5.	Unit:	in
6.	Body Mass Index:	[24.1]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[119]
	Diastolic:	[77]
	BP Position:	SITTING
	Pulse:	[74]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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: Jun/12/2020
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	[BNBTS3]
5.b	Sample ID	[BNBTS4]
5.c	Sample ID	[BNYG2B]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: MICROBIOLOGY SPECIMEN

Form Version: 22-Apr-2020 21:04

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date of Collection	Specimen Type	Assay Code and Description	Device Type	Result	Form Instance
1.	Jun/12/2020	BLOOD	SEVERE ACUTE RESP SYNDROME C ORONAVIRUS 2	SARS-COV-2 DIAGNOS TIC TEST	NEGATI VE	Repeating Pages

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: MICROBIOLOGY SPECIMEN

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

Microbiology Specimen

1.	Actual Date of Collection:	Jun/12/2020
2.	Specimen Type:	BLOOD
3.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
4.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
5.	Test Result:	NEGATIVE
6.	Comments/Findings/Details:	[]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: CENTRAL LAB SAMPLE COLLECTION - BASELINE

Form Version: 06-Jun-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Central Lab Sample Collection

1.	Collection Date:	Jun/12/2020
2.	Specimen Type:	BLOOD

Lab Test

3.a	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	BLOOD CHEMISTRY
	Was the lab sub-panel collected?:	YES
3.b	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	VIROLOGY
	Was the lab sub-panel collected?:	YES
3.c	Lab Panel:	HEMATOLOGY
	Lab Sub-Panel:	DIFFERENTIAL
	Was the lab sub-panel collected?:	YES

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jun/12/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jun/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jun/24/2020
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Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE
	Result:	NORMAL
2.b	Body System Examined:	SKIN
	Result:	NORMAL
2.c	Body System Examined:	HEAD
	Result:	NORMAL
2.d	Body System Examined:	EYES
	Result:	NORMAL
2.e	Body System Examined:	EARS
	Result:	NOT DONE
2.f	Body System Examined:	NOSE
	Result:	NORMAL
2.g	Body System Examined:	THROAT
	Result:	NORMAL
2.h	Body System Examined:	HEART
	Result:	NORMAL
2.i	Body System Examined:	LUNGS
	Result:	NORMAL
2.j	Body System Examined:	ABDOMEN
	Result:	NORMAL
2.k	Body System Examined:	MUSCULOSKELETAL
	Result:	NOT DONE

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

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2.1	Body System Examined:	EXTREMITIES
	Result:	NORMAL
2 m	Body System Examined:	NEUROLOGICAL
	Result:	NOT DONE
2 n	Body System Examined:	LYMPH NODES
	Result:	NORMAL

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.leviscc

Form: VITAL SIGNS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jun/24/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[118]
	Diastolic:	[59]
	BP Position:	SITTING
	Pulse:	[95]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 06-Jun-2020 00:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jun/24/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jun/24/2020
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	[BN8F6Z]
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: MICROBIOLOGY SPECIMEN

Form Version: 22-Apr-2020 21:05

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jun/24/2020	SWABBED MATERIAL	NASAL CAVITY	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:05

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: MICROBIOLOGY SPECIMEN

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

Microbiology Specimen

1.	Actual Date of Collection:	Jun/24/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASAL CAVITY
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	CEPHEID XPRT XPRESS SARS-COV-2 TEST
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Jun/24/2020
2.	Randomization Number:	[2303]
3.	Randomization Group:	[Stage 1, Age 18 to 55, Medium dose level (30mcg), 21 Day (BNT162b2 or PBO)]

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: STRATIFICATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Stratification

1.	Select appropriate response - Randomization Stage	Stage 1
2.	Select appropriate response - Randomization Age Group	Age 18 to 55
3.	Select appropriate response - Randomization Dose	Medium dose level (30mcg)
4.	Select appropriate response - Randomization Dose Group	21 Day
5.	Select appropriate response - BNT Number	(BNT162b2 or PBO)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jun/24/2020
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	[BN8F72]
5.b	Sample ID	[BN8F73]
5.c	Sample ID	[BN8F74]
5.d	Sample ID	[BN8F75]
5.e	Sample ID	[BN8F76]
5.f	Sample ID	[BNYG98]
5.g	Sample ID	[BNYG99]
5.h	Sample ID	[BNYG9B]
5.i	Sample ID	[BNYG9C]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jun/24/2020 11:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[0.5]
9.	Unit:	mL
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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jun/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jun/25/2020
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Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE
	Result:	NORMAL
2.b	Body System Examined:	SKIN
	Result:	NORMAL
2.c	Body System Examined:	HEAD
	Result:	NORMAL
2.d	Body System Examined:	EYES
	Result:	NORMAL
2.e	Body System Examined:	EARS
	Result:	NOT DONE
2.f	Body System Examined:	NOSE
	Result:	NOT DONE
2.g	Body System Examined:	THROAT
	Result:	NOT DONE
2.h	Body System Examined:	HEART
	Result:	NOT DONE
2.i	Body System Examined:	LUNGS
	Result:	NOT DONE
2.j	Body System Examined:	ABDOMEN
	Result:	NOT DONE
2.k	Body System Examined:	MUSCULOSKELETAL
	Result:	NOT DONE

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.1	Body System Examined:	EXTREMITIES
	Result:	NORMAL
2 m	Body System Examined:	NEUROLOGICAL
	Result:	NOT DONE
2 n	Body System Examined:	LYMPH NODES
	Result:	NORMAL

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: VITAL SIGNS

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.leviscc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jun/25/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[99.0]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[107]
	Diastolic:	[59]
	BP Position:	SITTING
	Pulse:	[83]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 19-Jun-2020 21:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CENTRAL LAB SAMPLE COLLECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Central Lab Sample Collection

1.	Collection Date:	Jun/25/2020
2.	Specimen Type:	BLOOD

Lab Test

3.a	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	BLOOD CHEMISTRY
	Was the lab sub-panel collected?:	YES
3.b	Lab Panel:	HEMATOLOGY
	Lab Sub-Panel:	DIFFERENTIAL
	Was the lab sub-panel collected?:	YES

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jul/1/2020
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Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE
	Result:	NORMAL
2.b	Body System Examined:	SKIN
	Result:	NORMAL
2.c	Body System Examined:	HEAD
	Result:	NORMAL
2.d	Body System Examined:	EYES
	Result:	NORMAL
2.e	Body System Examined:	EARS
	Result:	NOT DONE
2.f	Body System Examined:	NOSE
	Result:	NOT DONE
2.g	Body System Examined:	THROAT
	Result:	NOT DONE
2.h	Body System Examined:	HEART
	Result:	NOT DONE
2.i	Body System Examined:	LUNGS
	Result:	NOT DONE
2.j	Body System Examined:	ABDOMEN
	Result:	NOT DONE
2.k	Body System Examined:	MUSCULOSKELETAL
	Result:	NOT DONE

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.1	Body System Examined:	EXTREMITIES
	Result:	NORMAL
2 m	Body System Examined:	NEUROLOGICAL
	Result:	NOT DONE
2 n	Body System Examined:	LYMPH NODES
	Result:	NORMAL

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: VITAL SIGNS

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Vital Signs

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

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	EAR
	Systolic:	[111]
	Diastolic:	[62]
	BP Position:	SITTING
	Pulse:	[77]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 19-Jun-2020 21:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CENTRAL LAB SAMPLE COLLECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Central Lab Sample Collection

1.	Collection Date:	Jul/1/2020
2.	Specimen Type:	BLOOD

Lab Test

3.a	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	BLOOD CHEMISTRY
	Was the lab sub-panel collected?:	YES
3.b	Lab Panel:	HEMATOLOGY
	Lab Sub-Panel:	DIFFERENTIAL
	Was the lab sub-panel collected?:	YES

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/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	[BN8D04]
5.b	Sample ID	[BN8D05]
5.c	Sample ID	[BN8D06]
5.d	Sample ID	[BN8D07]
5.e	Sample ID	[BN8D08]
5.f	Sample ID	[BNYG7F]
5.g	Sample ID	[BNYG7G]
5.h	Sample ID	[BNYG7H]
5.i	Sample ID	[BNYFPY]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jul/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: PHYSICAL EXAMINATION

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jul/15/2020
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Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE
	Result:	NORMAL
2.b	Body System Examined:	SKIN
	Result:	NORMAL
2.c	Body System Examined:	HEAD
	Result:	NORMAL
2.d	Body System Examined:	EYES
	Result:	NORMAL
2.e	Body System Examined:	EARS
	Result:	NOT DONE
2.f	Body System Examined:	NOSE
	Result:	NOT DONE
2.g	Body System Examined:	THROAT
	Result:	NOT DONE
2.h	Body System Examined:	HEART
	Result:	NOT DONE
2.i	Body System Examined:	LUNGS
	Result:	NORMAL
2.j	Body System Examined:	ABDOMEN
	Result:	NOT DONE
2.k	Body System Examined:	MUSCULOSKELETAL
	Result:	NOT DONE

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.1	Body System Examined:	EXTREMITIES
	Result:	NORMAL
2 m	Body System Examined:	NEUROLOGICAL
	Result:	NOT DONE
2 n	Body System Examined:	LYMPH NODES
	Result:	NORMAL

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:54

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: VITAL SIGNS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/15/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[108]
	Diastolic:	[70]
	BP Position:	SITTING
	Pulse:	[81]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jun-2020 00:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jul/15/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jul/15/2020
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	[BGJFYF]
-----	-----------	----------

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: MICROBIOLOGY SPECIMEN

Form Version: 22-Apr-2020 21:05

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Jul/15/2020	SWABBED MATERIAL	NASAL CAVITY	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:05

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: MICROBIOLOGY SPECIMEN

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

Microbiology Specimen

1.	Actual Date of Collection:	Jul/15/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASAL CAVITY
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	CEPHEID XPRT XPRESS SARS-COV-2 TEST
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:52

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CENTRAL LAB SAMPLE COLLECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Central Lab Sample Collection

1.	Collection Date:	Jul/15/2020
2.	Specimen Type:	BLOOD

Lab Test

3.a	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	BLOOD CHEMISTRY
	Was the lab sub-panel collected?:	YES
3.b	Lab Panel:	HEMATOLOGY
	Lab Sub-Panel:	DIFFERENTIAL
	Was the lab sub-panel collected?:	YES

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/15/2020
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	[BGJFYH]
5.b	Sample ID	[BGJFYJ]
5.c	Sample ID	[BGJFYK]
5.d	Sample ID	[BGJFYL]
5.e	Sample ID	[BGJFYM]
5.f	Sample ID	[BNYF8X]
5.g	Sample ID	[BNYF8Y]
5.h	Sample ID	[BNYF8Z]
5.i	Sample ID	[BNYF90]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jul/15/2020 09:46
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[0.5]
9.	Unit:	mL
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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jul/22/2020
----	------------	-------------

Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE
	Result:	NORMAL
2.b	Body System Examined:	SKIN
	Result:	NORMAL
2.c	Body System Examined:	HEAD
	Result:	NORMAL
2.d	Body System Examined:	EYES
	Result:	NORMAL
2.e	Body System Examined:	EARS
	Result:	NOT DONE
2.f	Body System Examined:	NOSE
	Result:	NOT DONE
2.g	Body System Examined:	THROAT
	Result:	NOT DONE
2.h	Body System Examined:	HEART
	Result:	NOT DONE
2.i	Body System Examined:	LUNGS
	Result:	NOT DONE
2.j	Body System Examined:	ABDOMEN
	Result:	NOT DONE
2.k	Body System Examined:	MUSCULOSKELETAL
	Result:	NORMAL

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.1	Body System Examined:	EXTREMITIES
	Result:	NORMAL
2 m	Body System Examined:	NEUROLOGICAL
	Result:	NORMAL
2 n	Body System Examined:	LYMPH NODES
	Result:	NORMAL

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: VITAL SIGNS

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

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

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[103]
	Diastolic:	[63]
	BP Position:	SITTING
	Pulse:	[69]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 17-Jul-2020 21:53

Site No: 1003

Subject No: 10031065

Generated By: pfe.leviscc

Form: CENTRAL LAB SAMPLE COLLECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Central Lab Sample Collection

1.	Collection Date:	Jul/22/2020
2.	Specimen Type:	BLOOD

Lab Test

3.a	Lab Panel:	CLINICAL CHEMISTRY
	Lab Sub-Panel:	BLOOD CHEMISTRY
	Was the lab sub-panel collected?:	YES
3.b	Lab Panel:	HEMATOLOGY
	Lab Sub-Panel:	DIFFERENTIAL
	Was the lab sub-panel collected?:	YES

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BGJG6Z]
5.b	Sample ID	[BGJG70]
5.c	Sample ID	[BGJG71]
5.d	Sample ID	[BGJG72]
5.e	Sample ID	[BGJG73]
5.f	Sample ID	[BNYFG5]
5.g	Sample ID	[BNYFG6]
5.h	Sample ID	[BNYFG7]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jul/29/2020
----	------------	-------------

Physical Examination Result

2.a	Body System Examined:	GENERAL APPEARANCE
	Result:	NORMAL
2.b	Body System Examined:	SKIN
	Result:	NORMAL
2.c	Body System Examined:	HEAD
	Result:	NORMAL
2.d	Body System Examined:	EYES
	Result:	NORMAL
2.e	Body System Examined:	EARS
	Result:	NOT DONE
2.f	Body System Examined:	NOSE
	Result:	NOT DONE
2.g	Body System Examined:	THROAT
	Result:	NOT DONE
2.h	Body System Examined:	HEART
	Result:	NOT DONE
2.i	Body System Examined:	LUNGS
	Result:	NOT DONE
2.j	Body System Examined:	ABDOMEN
	Result:	NOT DONE
2.k	Body System Examined:	MUSCULOSKELETAL
	Result:	NOT DONE

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.1	Body System Examined:	EXTREMITIES
	Result:	NORMAL
2 m	Body System Examined:	NEUROLOGICAL
	Result:	NOT DONE
2 n	Body System Examined:	LYMPH NODES
	Result:	NORMAL

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VITAL SIGNS

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/29/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[99.1]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[100]
	Diastolic:	[70]
	BP Position:	SITTING
	Pulse:	[84]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/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	[BGJWB4]
5.b	Sample ID	[BGJWB5]
5.c	Sample ID	[BGJWB6]
5.d	Sample ID	[BGJWB7]
5.e	Sample ID	[BGJWB8]
5.f	Sample ID	[BNYFK6]
5.g	Sample ID	[BNYFK7]
5.h	Sample ID	[BNYFK8]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V7_MONTH1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V7_MONTH1_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[low draw]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP57GS]
5.b	Sample ID	[BP57GT]
5.c	Sample ID	[BP57GV]
5.d	Sample ID	[BP57GW]
5.e	Sample ID	[BP57GX]
5.f	Sample ID	[BKDZ5T]
5.g	Sample ID	[BKDZ5V]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8_MONTH6_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V8_MONTH6_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYLH4]
5.b	Sample ID	[BNWKSX]
5.c	Sample ID	[BNWKSX]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:11

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: INFORMED CONSENT - BOOSTER

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent - Booster

1.	Consent Was:	OBTAINED Date Written Consent Obtained Mar/3/2021
----	--------------	---

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:11

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - BOOSTER

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:10

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING FOR BOOSTER DOSE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening for Booster Dose

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

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:16

Site No: 1003

Subject No: 10031065

Generated By: pfe.leviscc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Mar/3/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/3/2021
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	[BPYLTM]
5.b	Sample ID	[BVR36V]
5.c	Sample ID	[BVR36W]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/3/2021
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	[BPYLTK]
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/3/2021 08:44
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8B_WEEK1_POSTVAX3

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V8B_WEEK1_POSTVAX3

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/10/2021
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	[BPYLVT]
5.b	Sample ID	[BVR394]
5.c	Sample ID	[BVR395]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8C_MONTH1_POSTVAX3

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V8C_MONTH1_POSTVAX3

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V8C_MONTH1_POSTVAX3

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 20-Feb-2021 02:24

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V9_MONTH12_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V9_MONTH12_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V10_MONTH24_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V10_MONTH24_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

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

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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:	[]
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Health Care Utilization

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jul/16/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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	Jul/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jul/16/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Jul/16/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Jul/16/2020 Contact Outcome: VISIT NOT REQUIRED, INVESTIGATOR DECISION
3.	Comments:	[Pt. Report: mild fever of (100.4-101.1 degree F), mild pain at injection site, severe fatigue and moderate headache. PI determined no site visit is clinically needed.]

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 22-Apr-2020 21:05

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Aug/19/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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	right arm pain	Jul/29/2020 09:40	YES	Repeating Pages
2.	ADVERSE EVENT	2	neuritis	Jul/29/2020 UNK:UNK	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[right arm pain]
4.	Start Date Time:	Jul/29/2020 09:40
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[neuritis]
4.	Start Date Time:	Jul/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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? NO Did this serious event result in persistent or significant disability/incapacity? YES 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: [related to study blood draw]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Not Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[2020449114]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Medication Error

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[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?	

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

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_BOOSTER_CONTACT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: UNPLANNED_BOOSTER_CONTACT -
Unscheduled

Form: BOOSTER DOSE TRIGGER FORM

Form Version: 20-Feb-2021 02:20

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Booster Dose Trigger Form

1.	Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?	The participant will return for consent/eligibility assessment for the booster dose visit
----	--	---

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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:	

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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?	

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/8/2021
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, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/8/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: BOOSTER_EOT - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Aug/19/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	----------------------	------	------	--------

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1.a	Jun-22-2020 07:18:47 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Line to be removed ----- Not Applicable
1.a	Jun-22-2020 07:18:25 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	line should be removed
1.a	Jun-16-2020 07:31:40 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Line 2 overlap ----- Not Applicable

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1.a	Jun-22-2020 07:18:47 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Line to be removed Not Applicable
1.a	Jun-22-2020 07:18:25 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	line should be removed
1.a	Jun-16-2020 07:31:40 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Line 2 overlap Not Applicable

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1.a	Jun-22-2020 07:18:47 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Line to be removed Not Applicable
1.a	Jun-22-2020 07:18:25 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	line should be removed
1.a	Jun-16-2020 07:31:40 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Line 2 overlap Not Applicable

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1.a	Jun-22-2020 07:18:47 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Line to be removed Not Applicable
1.a	Jun-22-2020 07:18:25 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	line should be removed
1.a	Jun-16-2020 07:31:40 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Line 2 overlap Not Applicable

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - BASELINE - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No medications at this time
			Not Applicable

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - BASELINE - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No medications at this time <hr/> Not Applicable

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - BASELINE - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - BASELINE - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No medications at this time <hr/> Not Applicable

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - BASELINE - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - BASELINE - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - BASELINE - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - BASELINE - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
7	Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: CONCOMITANT MEDICATIONS - BASELINE - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
8	Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - BASELINE - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
9	Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No medications at this time <hr/> Not Applicable

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:11

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - BOOSTER - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-03-2021 10:42:06 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lauren Mitchell	N/A	Nov-30-2020 07:38:31 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Edward Walsh	Approved	Nov-13-2020 13:24:11 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
--------------	----------	---	------	--------

Affidavit:

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

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

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

Mary Criddle	N/A	Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Edward Walsh	Approved	Nov-03-2020 16:55:32 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Mary Criddle	N/A	Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (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, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Affidavit:

N/A

Edward Walsh	Approved	Aug-24-2020 21:20:25 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jun-2020 00:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jun-12-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 27 MAY 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jun-12-2020 13:24:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: STAGE 1 SENTINEL COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: OBTAINED Date Written Consent Obtained Jun/12/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

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
Jun-12-2020 13:24:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10031065	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jun-12-2020 13:24:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1968	Screening Log Entry

3. Sex:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	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
Jun-12-2020 13:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: WHITE	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Jun-12-2020 13:25:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/12/2020	Initial Entry

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Inclusion Number: Criterion Description: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) Criterion met?: Criterion ID: IN01A00 (For Pfizer use only):	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

I.a Criterion met?

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry
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I.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: IN01A00	Initial Entry

I.b

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Inclusion Number: 2 Criteria Description: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures Criteria met?: YES Criteria ID: (For Pfizer use only): IN02A00	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

I.b Inclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 2	Initial Entry

I.b Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

I.b Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

I.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: IN02A00	Initial Entry

I.c

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Inclusion Number: Criterion: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			Criteria on met?: Criteria on ID: (For Pfizer use only):	
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I.c Inclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

I.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Inclusion Number 4	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			mber: Criteria Description: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol Criteria met?: YES Criteria ID: (For Pfizer use only): IN04A00	
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I.d Inclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 4	Initial Entry

I.d Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

I.d Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

I.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: IN04A00	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.a

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: Criterion Description: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation Criterion met?: Criterion ID: EX01A00 (For Pfizer use only):	Initial Entry

2.a Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.a Criterion ID: (For Pfizer use only)

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: Criterion Known infection with hum Description: an immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) Criterion met?: NO Criterion ID: (For Pfizer use only): EX02A00	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.b Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Known infection with human immuno deficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: Criterion Description: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) Criterion met?: NO	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			Criteria ID: EX03A00 (For Pfizer use only):	
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2.c Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: 4 Criterion Description: Receipt of medications intended to prevent COVID-19	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			Criterion met NO ?: Criterion ID: EX04A00 (For Pfizer use only):	
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2.d Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion 5 Number: Criterion D Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19 Criterion NO met?:	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

			Criterion I EX05A00 D: (For Pfizer use only):	
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2.e Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 5	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.e Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX05A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion 6 Number: Criterion Description: Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol) Criterion met?: NO	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Generated By: pfe.lewissc

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

			Criterion ID: (For Pfizer use only): EX06A01	
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2.f Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 6	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Sentinel participants in Stage 1 only: I ndividuals at high risk for severe COV ID-19 (full details in protocol)	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.f Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX06A01	Initial Entry

2.g

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclus 7 ion Nu mber:	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

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Form Version: 06-Jun-2020 00:48

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Subject No: 10031065

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

			<p>Criteria Description: Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)</p> <p>Criteria Met?: NO</p> <p>Criteria ID: (For Pfizer use only): EX07A00</p>	
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 7	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Sentinel participants in Stage 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel)	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.g Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX07A00	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Form Version: 06-Jun-2020 00:48

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Subject Initials: ---

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

2.h

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: 8 Criterion Description: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination Criterion met?: NO Criterion ID: (For Pfizer use only): EX08A00	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

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

2.h Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 8	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Immunocompromised individuals with known or suspected immunodeficiency , as determined by history and/or laboratory/physical examination	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.h Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX08A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: Criterion Description: Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention Criterion met?: NO	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

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Subject No: 10031065

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

			Criterion EX09A00 ID: (For Pfizer use only):	
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2.i Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 9	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

2.i Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EX09A00	Initial Entry

2.j

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Exclusion Number:	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			<p>Criteria on Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p>Criteria met? : NO</p> <p>Criteria ID: (For Pfizer use only): EX10A00</p>	
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2.j Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 10	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.j Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX10A00	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

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Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

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

[Back to Form](#)

2.k

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: 11 Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: (For Pfizer use only): EX11A00	Initial Entry

2.k Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 11	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Women who are pregnant or breastfeeding	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.k Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX11A00	Initial Entry

2.l

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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Form Version: 06-Jun-2020 00:48

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met? NO : Criterion ID: (For Pfizer use only): EX12A00	Initial Entry

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 12	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX12A00	Initial Entry

2.m

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids Criterion met?: Criterion ID: (For Pfizer use only): EX13A01	Initial Entry
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2.m Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 13	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.m Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX13A01	Initial Entry

2.n

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: 14 Criterion Description: Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids Criterion met?: NO Criterion ID (For Pfizer use only): EX22A01	Initial Entry
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2.n Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 14	Initial Entry

2.n Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids	Initial Entry

2.n Criterion met?:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.n Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX22A01	Initial Entry

2.o

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

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

Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: 15 Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study Criterion met? NO : Criterion ID: (EX14A01) For Pfizer use only):	Initial Entry
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

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

2.o Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 15	Initial Entry

2.o Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.o Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.o Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX14A01	Initial Entry

2.p

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: 16 Criterion Description: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation Criterion met?: NO	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

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Site No: 1003

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			Criterion ID: (F or Pfizer use only): EX15A01	
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2.p Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 16	Initial Entry

2.p Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.p Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.p Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX15A01	Initial Entry

2.q

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: 17 Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

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Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

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

			Criterion met?: Criterion EX16A01 ID: (For Pfizer use only):	
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2.q Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 17	Initial Entry

2.q Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.q Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.q Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX16A01	Initial Entry

2.r

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: 18	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			Criterion Description: Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit Criterion met?: NO Criterion ID: (For Pfizer use only): EX17A01	
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2.r Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 18	Initial Entry

2.r Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Sentinel participants in Stage 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit	Initial Entry

2.r Criterion met?:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.r Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX17A01	Initial Entry

2.s

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

<p>Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Megan Helf (pfe.ahelf)</p>	<p>Data Entry: Exclus 19 ion N umber : Criterion De Sentinel participants in Stage 1 only: Screening hematology /blood chemistry lab >=Grade 1 abnormality. Except Bilirubin, other stable Grade1 abnormalities may be considered eligible by Investigator Criterion m NO et?: Criterion ID EX18A01 : (For Pfizer use only):</p>	<p>Initial Entry</p>
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.s Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 19	Initial Entry

2.s Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Sentinel participants in Stage 1 only: S creening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bil irubin, other stable Grade1 abnormaliti es may be considered eligible by Inves tigator	Initial Entry

2.s Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.s Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX18A01	Initial Entry

2.t

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclus 20 ion Nu mber: Criter Sentinel participants in Stage ion De 1 only: Positive test for HIV, scripti hepatitis B surface antigen (H on: BsAg), hepatitis B core antib odies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			<p>Criterion met?:</p> <p>Criterion ID: (For Pfizer use only):</p>	
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2.t Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 20	Initial Entry

2.t Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Sentinel participants in Stage 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at screening visit	Initial Entry

2.t Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.t Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX19A01	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

2.u				
Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: Criterion Description: Sentinel participants in Stage 1 only: SARS-CoV-2 NAT-positive nasal swab within 24 hours before receipt of study intervention Criterion met?: Criterion ID: (For Pfizer use only): EX20A01	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.u Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 21	Initial Entry

2.u Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Sentinel participants in Stage 1 only: S ARS-CoV-2 NAAT-positive nasal swa b within 24 hours before receipt of stu dy intervention	Initial Entry

2.u Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.u Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX20A01	Initial Entry

2.v

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclus 22 ion Nu mber: Criteria Investigator site staff or Pfize on Des r employees directly involve criptio d in the conduct of the study, n: site staff otherwise supervise d by the investigator, and thei r respective family members Criteria NO on met ?:	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			Criteria ID: (For Pfizer use only) :	
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2.v Exclusion Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 22	Initial Entry

2.v Criterion Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.v Criterion met?

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.v Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jun-12-2020 13:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX21A01	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jun-12-2020 13:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jun-12-2020 13:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jun-12-2020 13:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Jul-02-2020 10:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Line/MH Number: Not Applicable Medical History Term: Not Applicable Start Date: Not Applicable Ongoing: Not Applicable	New Information (DELETED)
Jun-22-2020 07:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Not Applicable Medical History Term: Not Applicable Start Date: Not Applicable Ongoing: Not Applicable	Initial Entry
Jun-22-2020 07:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	Initial Entry
Jun-16-2020 07:31:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Not Applicable Medical History Term: Not Applicable Start Date: Not Applicable Ongoing: Not Applicable	Initial Entry
Jun-16-2020 07:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	Changed Information

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Jun-16-2020 07:31:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing: YES	Changed Information
Jun-16-2020 07:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: UNK/UNK/1982 Ongoing: YES	Changed Information
Jun-12-2020 13:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History Term: Wears Contacts PRN Start Date: UNK/UNK/1982 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Jul-02-2020 10:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	New Information (DELETED)
Jun-22-2020 07:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-22-2020 07:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Jun-16-2020 07:31:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jun-16-2020 07:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Jun-12-2020 13:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Jul-08-2020 13:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi TMS Query (pfe.noig_tmsquery)	Query 5: Closed	Response satisfies query
Jul-02-2020 10:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	New Information (DELETED)
Jul-02-2020 10:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	New Information
Jul-02-2020 09:27:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Josée Robillard tmsq (pfe.robilj01_tmsq)	Query 5: Reissued:Opened	If line is not applicable, please select 'delete' at the bottom of the page rather than adding NOT APPLICABLE.
Jun-22-2020 10:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 5: Answered	This line needs to be deleted. Therefore not applicable.
Jun-22-2020 09:26:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 5: Opened	Null Term: Verbatim term must not be null/blank.
Jun-22-2020 08:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 4: Closed	Discrepancy has been closed.
Jun-22-2020 07:18:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 4: Answered	Line should be removed

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Jun-22-2020 07:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry
Jun-22-2020 07:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry:	Initial Entry
Jun-19-2020 20:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 4: Opened	Null Term: Verbatim term must not be null/blank.
Jun-19-2020 19:21:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Closed	Discrepancy has been closed.
Jun-17-2020 01:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 2: Closed	Response satisfies query
Jun-16-2020 08:39:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 3: Answered	Original value is correct
Jun-16-2020 08:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Opened	Null Term: Verbatim term must not be null/blank.
Jun-16-2020 07:31:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry
Jun-16-2020 07:31:01 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

(US & Canada)				
Jun-16-2020 07:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry:	Changed Information
Jun-16-2020 06:08:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 2: Opened	This Medical History event appears to be a duplicate with overlapping dates with another Medical History event recorded on line 2. Please review if any updates are needed. If no updates are required, please clarify.
Jun-16-2020 06:07:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 1: Closed	Incorrect Query Text
Jun-16-2020 06:05:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW3858841;This Medical History event appears to be a duplicate with overlapping dates with another Medical History event recorded on line . Please review if any updates are needed. If no updates are required, please clarify.
Jun-12-2020 13:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Wears Contacts PRN	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

Jul-02-2020 10:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	New Information (DELETED)
Jun-22-2020 07:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry
Jun-22-2020 07:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry:	Initial Entry
Jun-16-2020 07:31:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry
Jun-16-2020 07:31:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry:	Changed Information
Jun-12-2020 13:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: UNK/UNK/1982	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Jul-02-2020 10:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	New Information (DELETED)
Jun-22-2020 07:18:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry
Jun-22-2020 07:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry:	Initial Entry
Jun-16-2020 07:31:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry
Jun-16-2020 07:31:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry:	Changed Information
Jun-12-2020 13:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

I.b

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jun-12-2020 13:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Wears Glasses Start Date: UNK/UNK/1982 Ongoing: YES	Initial Entry

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1.b Line/MH Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:32:46 (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
Jun-16-2020 06:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 1: Clo sed	Incorrect Query text.
Jun-16-2020 06:05:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW3858842;This Medical History event appears to be a duplicate with overlapping dates with another Medical History event recorded on line . Please review if any updates are needed. If no updates are required, please clarify.
Jun-12-2020 13:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Wears Glass es	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jun-12-2020 13:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: UNK/UNK/1982	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Jun-12-2020 13:32:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry
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I.c

Date	Location	User	Value	Reason
Jun-12-2020 13:33:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 3 ber: Medical Histo Deviated Septum - N ry Term: asal Surgery Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Jun-12-2020 13:33:20 (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
Jun-12-2020 13:33:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Deviated Septum - Nasal Surgery	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Jun-12-2020 13:33:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: UNK/UNK/2010	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Jun-12-2020 13:33:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Megan Helf	Data Entry: Not Applicable	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

(US & Canada)		(pfe.ahelf)	
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7. Dose Frequency:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:46

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Exam Date:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/12/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: GENERAL APPEARANCE	Initial Entry

2.a Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: SKIN Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:46

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: SKIN	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.c

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: HEAD Result: NORMAL	Initial Entry

2.c Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: HEAD	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.d

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: EYES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:46

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.e

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: EARS Result: NORMAL	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EARS	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.f

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: NOSE Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:46

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NOSE	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.g

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: THROAT Result: NORMAL	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: THROAT	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.h

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: HEART Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:46

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: HEART	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.i

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: LUNGS Result: NORMAL	Initial Entry

2.i Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.j

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined ABDOME : N Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:46

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.k

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: MUSCULOSKELETAL Result: NORMAL	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: MUSCULOSKELETAL	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.l

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: EXTREMITIES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:46

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EXTREMITIES	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.m

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: NEUROLOGIC AL Result: NORMAL	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NEUROLOGICAL	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.n

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: LYMPH NOD ES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form Version: 06-Jun-2020 00:46

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: LYMPH NODES	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:34:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Jun/12/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 154.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 67.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 24.1	Initial Entry

7.a

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Record Identifier:: 1 Temperature: 98.4 Temperature Unit: F Temperature Location: FOREHEA : D Systolic:: 119 Diastolic:: 77 BP Position: SITTING Pulse:: 74	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 98.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: FOREHEAD	Initial Entry

7.a Systolic:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Megan Helf	Data Entry: 119	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 06-Jun-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

(US & Canada)		(pfe.ahelf)		
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7.a Diastolic:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 77	Initial Entry

7.a BP Position:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> SITTING	Initial Entry

7.a Pulse:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 74	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jun-12-2020 13:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-12-2020 13:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-12-2020 15:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-12-2020 13:35:22 (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.
Jun-12-2020 13:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Collection: Jun/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-12-2020 15:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNBTS3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: ELECTRONIC SAMPLE TRACKING - PRIOR COVID-19 INFECTION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-12-2020 15:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNBTS3	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jun-12-2020 15:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNBTS4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jun-12-2020 15:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNBTS4	Initial Entry

5.c

Date	Location	User	Value	Reason
Jun-12-2020 15:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYG2B	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jun-12-2020 15:54:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYG2B	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 22-Apr-2020 21:04

Form Status:

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-12-2020 13:35:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Form Created	

Header Text: c4591001

Visit: SCR

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/12/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: BLOOD	Initial Entry

3. Assay Code and Description:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROM E CORONAVIRUS 2	Initial Entry

4. Device Type:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

5. Test Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: CENTRAL LAB SAMPLE COLLECTION - BASELINE - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Collection Date:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/12/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Category for Lab CLINICAL CHE Test: MISTRY Subcategory for BLOOD CHEMI Lab Test: STRY Lab Sub-Panel C YES ollected:	Initial Entry

3.a Lab Panel:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: BLOOD CHEMISTRY	Initial Entry

3.a Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** SCR**Form:** CENTRAL LAB SAMPLE COLLECTION - BASELINE - eCRF
Audit Trail History**Form Version:** 06-Jun-2020 00:47**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031065**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry
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3.b

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Category for Lab Test: CLINICAL CHEMISTRY Subcategory for Lab Test: VIROLOGY Lab Sub-Panel C collected: YES	Initial Entry

3.b Lab Panel:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

3.b Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: VIROLOGY	Initial Entry

3.b Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

3.c

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Category for Lab Test: HEMATOLOGY Subcategory for Lab Test: DIFFERENTIAL	Initial Entry

Header Text: c4591001

Visit: SCR

Form: CENTRAL LAB SAMPLE COLLECTION - BASELINE - eCRF
Audit Trail History

Form Version: 06-Jun-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

			Lab Sub-Panel Collected: YES	
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3.c Lab Panel:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: HEMATOLOGY	Initial Entry

3.c Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: DIFFERENTIAL	Initial Entry

3.c Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** SCR**Form Version:** 06-Jun-2020 00:47**Site No:** 1003**Subject No:** 10031065**Generated By:** pfe.levissc**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jun-12-2020 13:35:48 (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
Jun-12-2020 13:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/12/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jun-12-2020 13:35:48 (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
Jun-12-2020 13:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jun-12-2020 13:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113	Initial Entry

Header Text: c4591001

Visit: SCR

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

Form Version: 06-Jun-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

			Result: NEGATIVE	
			Not Done:	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jun-12-2020 13:35:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Jun-24-2020 08:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jun/24/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Exam Date:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Jun/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examined: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: GENERAL APPEARANCE	Initial Entry

2.a Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examined: SKIN Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: SKIN	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.c

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined HEAD : Result: NORMA L	Initial Entry

2.c Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: HEAD	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.d

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined EYES : Result: NORMA L	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.e

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine EARS d: Result: NOT DON E	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: EARS	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.f

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined NOSE : Result: NORMA L	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOSE	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.g

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined THROAT : Result: NORMA L	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: THROAT	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.h

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined HEART : Result: NORMA L	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: HEART	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.i

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined LUNGS : Result: NORMA L	Initial Entry

2.i Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.j

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine ABDOME d: N Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.k

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: MUSCULOSKELETAL Result: NOT DONE	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: MUSCULOSKELETAL	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.l

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: EXTREMITIES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: EXTREMITIES	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.m

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: NEUROLOGICAL Result: NOT DONE	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NEUROLOGICAL	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.n

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: LYMPH NODES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LYMPH NODES	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 19-Jun-2020 21:48

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: VITAL SIGNS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jun-24-2020 08:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jun/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-24-2020 08:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Record Identifier:: 1 Temperature: 98.1 Temperature Unit: F Temperature Locatio FOREHEA n:: D Systolic:: 118 Diastolic:: 59 BP Position: SITTING Pulse:: 95	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jun-24-2020 08:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jun-24-2020 08:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: 98.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jun-24-2020 08:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jun-24-2020 08:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: FOREHEAD	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jun-24-2020 08:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 118	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jun-25-2020 01:00:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 1: Closed	Response satisfies query
Jun-24-2020 12:10:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	Original value is correct
Jun-24-2020 08:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 59 is outside of Normal Range 60 - 90.
Jun-24-2020 08:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 59	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jun-24-2020 08:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
Jun-24-2020 08:49:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 95	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 06-Jun-2020 00:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Jun-24-2020 08:50:08 (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
Jun-24-2020 08:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jun-24-2020 08:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jun/24/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jun-24-2020 08:50:08 (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
Jun-24-2020 08:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jun-24-2020 08:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_S
Form Version: 06-Jun-2020 00:47
Site No: 1003
Subject No: 10031065
Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1003) Rochester Regional HealthRochester General Hospital
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:04

			Result:: NEGATIVE Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jun-24-2020 08:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jun-24-2020 08:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jun-24-2020 08:50:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jun-24-2020 08:50:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-24-2020 08:50:31 (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
Jun-24-2020 11:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-24-2020 08:50:31 (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.
Jun-24-2020 08:50:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: YES Date of Collection: Jun/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-24-2020 11:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BN8F6Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-24-2020 11:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BN8F6Z	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:05

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Status:

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jun-24-2020 12:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Form Created	

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jun-24-2020 12:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jun/24/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-24-2020 12:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jun-24-2020 12:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL CAVITY	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jun-24-2020 12:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROM E CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jun-24-2020 12:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jun-24-2020 12:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CEPHEID XPRT XPRESS SARS-C OV-2 TEST	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:05

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Jun-24-2020 12:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NEGATIVE	Initial Entry
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Jun-24-2020 12:12:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jun/24/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jun-25-2020 11:41:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_07
Jun-25-2020 07:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jun-25-2020 07:17:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 2303	Transcription Error
Jun-25-2020 01:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW3900311;Randomization Number appears to be a duplicate with Subject 10031072. Please confirm the number has been entered correctly or clarify.
Jun-24-2020 12:12:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 2302	Initial Entry

3. Randomization Group:

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Jun-24-2020 12:13:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Stage 1, Age 18 to 55, Medium dose level (30mcg), 21 Day (BNT162b2 or PBO)	Initial Entry
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: STRATIFICATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Randomization Stage

Date	Location	User	Value	Reason
Jun-24-2020 12:13:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Stage 1	Initial Entry

2. Select appropriate response - Randomization Age Group

Date	Location	User	Value	Reason
Jun-24-2020 12:13:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Age 18 to 55	Initial Entry

3. Select appropriate response - Randomization Dose

Date	Location	User	Value	Reason
Jun-24-2020 12:13:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Medium dose level (30mcg)	Initial Entry

4. Select appropriate response - Randomization Dose Group

Date	Location	User	Value	Reason
Jun-24-2020 12:13:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: 21 Day	Initial Entry

5. Select appropriate response - BNT Number

Date	Location	User	Value	Reason
Jun-24-2020 12:13:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: (BNT162b2 or PBO)	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jun-24-2020 11:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-24-2020 11:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-24-2020 11:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-24-2020 11:54:29 (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.
Jun-24-2020 11:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: YES Date of Collection: Jun/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-24-2020 11:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BN8F72	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-24-2020 11:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BN8F72	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jun-24-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BN8F73	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 11:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BN8F73	Initial Entry

5.c

Date	Location	User	Value	Reason
Jun-24-2020 11:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BN8F74	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 11:54:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BN8F74	Initial Entry

5.d

Date	Location	User	Value	Reason
Jun-24-2020 11:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BN8F75	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 11:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BN8F75	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

5.e

Date	Location	User	Value	Reason
Jun-24-2020 11:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BN8F76	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 11:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BN8F76	Initial Entry

5.f

Date	Location	User	Value	Reason
Jun-24-2020 11:55:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BNYG98	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 11:55:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BNYG98	Initial Entry

5.g

Date	Location	User	Value	Reason
Jun-24-2020 11:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BNYG99	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 11:55:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BNYG99	Initial Entry

5.h

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-24-2020 11:55:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYG9B	Initial Entry
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5.h Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 11:55:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYG9B	Initial Entry

5.i

Date	Location	User	Value	Reason
Jun-24-2020 11:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYG9C	Initial Entry

5.i Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 11:55:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYG9C	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jun-24-2020 12:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jun-24-2020 12:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jun-24-2020 12:15:03 (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
Jun-24-2020 12:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jun/24/2020 11:32	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jun-24-2020 12:15:03 (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
Jun-24-2020 12:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jun-24-2020 12:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jun-24-2020 12:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 0.5	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jun-24-2020 12:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: mL	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jun-24-2020 12:15:03 (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
Jun-24-2020 12:15:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: YES	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Jun-25-2020 13:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/25/2020	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Exam Date:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/25/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: GENERAL APPEARANCE	Initial Entry

2.a Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: SKIN Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: SKIN	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.c

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: HEAD Result: NORMAL	Initial Entry

2.c Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: HEAD	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.d

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: EYES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.e

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examine EARS d: Result: NOT DON E	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: EARS	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

2.f

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examine NOSE d: Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOSE	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

2.g

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examine THROAT d: Result: NOT DON E	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: THROAT	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

2.h

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examine HEART d: Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: HEART	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

2.i

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examine LUNGS d: Result: NOT DON E	Initial Entry

2.i Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

2.j

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examine ABDOME d: N Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

2.k

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: MUSCULOSKELETAL Result: NOT DONE	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: MUSCULOSKELETAL	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

2.l

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: EXTREMITIES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: EXTREMITIES	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.m

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Exam NEUROLOGI ined: CAL Result: NOT DONE	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NEUROLOGICAL	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

2.n

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Exami LYMPH NOD ned: ES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: LYMPH NODES	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jun-25-2020 13:53:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/25/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-25-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Record Identifier:: 1 Temperature: 99.0 Temperature Unit: F Temperature Location FOREHEA :: D Systolic:: 107 Diastolic:: 59 BP Position: SITTING Pulse:: 83	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 99.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: F	Initial Entry

2.a Temperature Location:

090177e196ae3d68\Final\On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jun-25-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: FOREHEAD	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 107	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jun-26-2020 03:04:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 1: Closed	Response satisfies query
Jun-25-2020 13:53:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Query 1: Answered	Original value is correct
Jun-25-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 59 is outside of Normal Range 60 - 90.
Jun-25-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 59	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
Jun-25-2020 13:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 83	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 19-Jun-2020 21:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Collection Date:

Date	Location	User	Value	Reason
Jun-25-2020 13:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/25/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-25-2020 13:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jun-25-2020 13:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Category for Lab CLINICAL CHE Test: MISTRY Subcategory for BLOOD CHEMI Lab Test: STRY Lab Sub-Panel C YES ollected:	Initial Entry

3.a Lab Panel:

Date	Location	User	Value	Reason
Jun-25-2020 13:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-25-2020 13:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: BLOOD CHEMISTRY	Initial Entry

3.a Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jun-25-2020 13:53:04	ACV0PFEINFP6000	Emily	Data Entry:	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001
Visit: V2_DAY2_POSTVAX1_S **Form:** CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History
Form Version: 19-Jun-2020 21:47 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital
Subject No: 10031065 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)		Pierce (pfe.epierce)	YES	
---	--	-------------------------	-----	--

3.b

Date	Location	User	Value	Reason
Jun-25-2020 13:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Category for Lab Test: HEMATOLOGY Subcategory for Lab Test: DIFFERENTIAL Lab Sub-Panel Collected: YES	Initial Entry

3.b Lab Panel:

Date	Location	User	Value	Reason
Jun-25-2020 13:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: HEMATOLOGY	Initial Entry

3.b Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-25-2020 13:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: DIFFERENTIAL	Initial Entry

3.b Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jun-25-2020 13:53:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Jul-01-2020 13:18:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jul/1/2020	Initial Entry

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Exam Date:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jul/1/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: GENERAL APPEARANCE	Initial Entry

2.a Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: SKIN Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> SKIN	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NORMAL	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Body System Examined: HEAD Result: NORMAL	Initial Entry

2.c Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> HEAD	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NORMAL	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Body System Examined: EYES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined EARS : Result: NOT DON E	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EARS	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NOT DONE	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined NOSE : Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NOSE	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NOT DONE	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Body System Examined THROAT : Result: NOT DONE	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> THROAT	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NOT DONE	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Body System Examined HEART : Result: NOT DONE	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: HEART	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NOT DONE	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined LUNGS : Result: NOT DON E	Initial Entry

2.i Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NOT DONE	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined ABDOME : N Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NOT DONE	Initial Entry

2.k

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: MUSCULOSKELETAL Result: NOT DONE	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: MUSCULOSKELETAL	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NOT DONE	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: EXTREMITIES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EXTREMITIES	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: NEUROLOGICAL Result: NOT DONE	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NEUROLOGICAL	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NOT DONE	Initial Entry

2.n

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: LYMPH NODES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: LYMPH NODES	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

Header Text: c4591001**Visit:** V3_WEEK1_POSTVAX1_S**Form Version:** 19-Jun-2020 21:48**Site No:** 1003**Subject No:** 10031065**Generated By:** pfe.levissc**Form:** VITAL SIGNS - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jul-01-2020 13:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jul/1/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-01-2020 13:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Location:: EAR Systolic:: 111 Diastolic:: 62 BP Position: SITTING Pulse:: 77	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: F	Initial Entry

2.a Temperature Location:

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 19-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jul-01-2020 13:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EAR	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 111	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 62	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 77	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 19-Jun-2020 21:47

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Collection Date:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jul/1/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jul-01-2020 13:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Category for Lab Test: CLINICAL CHEMISTRY Subcategory for Lab Test: BLOOD CHEMISTRY Lab Sub-Panel C collected: YES	Initial Entry

3.a Lab Panel:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: BLOOD CHEMISTRY	Initial Entry

3.a Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:39	ACV0PFEINFP6000	Megan	Data Entry:	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001
Visit: V3_WEEK1_POSTVAX1_S **Form:** CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History
Form Version: 19-Jun-2020 21:47 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital
Subject No: 10031065 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)		Helf (pfe.ahelf)	YES	
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3.b

Date	Location	User	Value	Reason
Jul-01-2020 13:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Category for Lab Test: HEMATOLOGY Subcategory for Lab Test: DIFFERENTIAL Test: AL Lab Sub-Panel Collected: YES	Initial Entry

3.b Lab Panel:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: HEMATOLOGY	Initial Entry

3.b Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: DIFFERENTIAL	Initial Entry

3.b Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jul-01-2020 13:19:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jul-01-2020 13:19:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-01-2020 13:19:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-01-2020 16:54:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-01-2020 13:19:45 (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.
Jul-01-2020 13:19:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Collection: Jul/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-01-2020 16:54:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BN8D04	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-01-2020 16:54:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BN8D04	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jul-01-2020 16:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BN8D05	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-01-2020 16:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BN8D05	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-01-2020 16:54:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BN8D06	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jul-01-2020 16:54:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BN8D06	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-01-2020 16:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BN8D07	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jul-01-2020 16:54:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BN8D07	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

5.e

Date	Location	User	Value	Reason
Jul-01-2020 16:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BN8D08	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jul-01-2020 16:54:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BN8D08	Initial Entry

5.f

Date	Location	User	Value	Reason
Jul-01-2020 16:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYG7F	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Jul-01-2020 16:54:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYG7F	Initial Entry

5.g

Date	Location	User	Value	Reason
Jul-01-2020 16:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYG7G	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jul-01-2020 16:54:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYG7G	Initial Entry

5.h

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-01-2020 16:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYG7H	Initial Entry
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5.h Sample ID

Date	Location	User	Value	Reason
Jul-01-2020 16:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYG7H	Initial Entry

5.i

Date	Location	User	Value	Reason
Jul-01-2020 16:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYFPY	Initial Entry

5.i Sample ID

Date	Location	User	Value	Reason
Jul-01-2020 16:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYFPY	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Jul-15-2020 09:04:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jul/15/2020	Initial Entry

Header Text: c4591001**Visit:** V4_WEEK3_VAX2_S**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031065**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	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
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Symptom:: FAT IG UE	Initial Entry

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<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
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> <u>Symptom::</u> HEA DAC HE 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
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<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
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

2.d

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<u>Data Entry:</u> Symptom:: CH ILL S 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
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<u>Data Entry:</u> Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Symptom:

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<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
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<u>Data Entry:</u> Symptom:: DIA RR HE A Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<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
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06	ACV0PFEINFP6000	Mary Criddle	<u>Data Entry:</u>	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe mcriddle)	Symptom:: NEW OR WORSE ED MUSC LE PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NEW OR WORSE NED MUSCLE P AIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Symptom:

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (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
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the Su bject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: REDNESS	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** V4_WEEK3_VAX2_S**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031065**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	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
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Injection Site Reaction:: PAIN A T INJEC TION SI TE Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	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
Jul-15-2020 09:05:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Exam Date:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Jul/15/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examined: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: GENERAL APPEARANCE	Initial Entry

2.a Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examined: SKIN Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: SKIN	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined HEAD : Result: NORMA L	Initial Entry

2.c Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: HEAD	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined EYES : Result: NORMA L	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine EARS d: Result: NOT DON E	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: EARS	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine NOSE d: Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NOSE	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NOT DONE	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examine THROAT d: Result: NOT DON E	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: THROAT	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NOT DONE	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examine HEART d: Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: HEART	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined LUNGS : Result: NORMA L	Initial Entry

2.i Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine ABDOME d: N Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.k

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: MUSCULOSKELETAL Result: NOT DONE	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: MUSCULOSKELETAL	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: EXTREMITIES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: EXTREMITIES	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: NEUROLOGICAL Result: NOT DONE	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NEUROLOGICAL	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.n

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: LYMPH NODES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LYMPH NODES	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jul-15-2020 12:17:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

Header Text: c4591001**Visit:** V4_WEEK3_VAX2_S**Form Version:** 06-Jul-2020 21:54**Site No:** 1003**Subject No:** 10031065**Generated By:** pfe.levissc**Form:** VITAL SIGNS - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**I. Date:**

Date	Location	User	Value	Reason
Jul-15-2020 09:08:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jul-15-2020 09:08:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Jul/15/2020	Transcription Error
Jul-15-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital signs Date 14/Jul/2020 is not same as Date of Visit 15/Jul/2020. Please review and update as appropriate or clarify.
Jul-15-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Jul/14/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-15-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Record Identifier:: 1 Temperature: 98.7 Temperature Unit: F Temperature Locatio n:: FOREHEA D Systolic:: 108 Diastolic:: 70 BP Position: SITTING Pulse:: 81	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jul-15-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: 1	Initial Entry

2.a Temperature:

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jul-15-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> 98.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jul-15-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jul-15-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> FOREHEAD	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jul-15-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> 108	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jul-15-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> 70	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jul-15-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
Jul-15-2020 09:06:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> 81	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** V4_WEEK3_VAX2_S**Form Version:** 06-Jun-2020 00:47**Site No:** 1003**Subject No:** 10031065**Generated By:** pfe.levissc**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jul-15-2020 09:06:37 (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
Jul-15-2020 09:06:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jul-15-2020 09:06:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jul/15/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jul-15-2020 09:06:37 (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
Jul-15-2020 09:06:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jul-15-2020 09:06:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113	Initial Entry

Header Text: c4591001
Visit: V4_WEEK3_VAX2_S **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History
Form Version: 06-Jun-2020 00:47 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital
Subject No: 10031065 **Subject Initials:** ---
Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

			Result:: NEGATIVE Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jul-15-2020 09:06:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jul-15-2020 09:06:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jul-15-2020 09:06:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jul-15-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-15-2020 09:06:59 (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
Jul-15-2020 11:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-15-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-15-2020 09:06:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: YES Date of Collection: Jul/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-15-2020 11:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJFYF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-15-2020 11:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJFYF	Initial Entry
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Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 22-Apr-2020 21:05

Form Status:

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.leviscc

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jul-15-2020 11:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Form Created	

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jul-15-2020 11:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jul/15/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-15-2020 11:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jul-15-2020 11:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL CAVITY	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jul-15-2020 11:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROM E CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jul-15-2020 11:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jul-15-2020 11:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CEPHEID XPRT XPRESS SARS-C OV-2 TEST	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:05

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Jul-15-2020 11:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NEGATIVE	Initial Entry
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Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:52

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Collection Date:

Date	Location	User	Value	Reason
Jul-15-2020 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jul/15/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-15-2020 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jul-15-2020 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Category for Lab Test: CLINICAL CHEMISTRY Subcategory for Lab Test: BLOOD CHEMISTRY Lab Sub-Panel C collected: YES	Initial Entry

3.a Lab Panel:

Date	Location	User	Value	Reason
Jul-15-2020 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-15-2020 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: BLOOD CHEMISTRY	Initial Entry

3.a Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jul-15-2020 09:07:19	ACV0PFEINFP6000	Mary Criddle	Data Entry:	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe mcriddle)	YES	
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3.b

Date	Location	User	Value	Reason
Jul-15-2020 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Category for Lab Test: HEMATOLOGY Subcategory for Lab Test: DIFFERENTIAL Lab Sub-Panel Collected: YES	Initial Entry

3.b Lab Panel:

Date	Location	User	Value	Reason
Jul-15-2020 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: HEMATOLOGY	Initial Entry

3.b Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-15-2020 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: DIFFERENTIAL	Initial Entry

3.b Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jul-15-2020 09:07:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: YES	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jul-15-2020 09:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-15-2020 09:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-15-2020 11:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-15-2020 09:07:38 (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.
Jul-15-2020 09:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: YES Date of Collection: Jul/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-15-2020 11:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJFYH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-15-2020 11:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJFYH	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jul-15-2020 11:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJFYJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-15-2020 11:03:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJFYJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-15-2020 11:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJFYK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jul-15-2020 11:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJFYK	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-15-2020 11:03:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJFYL	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jul-15-2020 11:03:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJFYL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

5.e

Date	Location	User	Value	Reason
Jul-15-2020 11:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJFYM	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jul-15-2020 11:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJFYM	Initial Entry

5.f

Date	Location	User	Value	Reason
Jul-15-2020 11:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYF8X	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Jul-15-2020 11:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYF8X	Initial Entry

5.g

Date	Location	User	Value	Reason
Jul-15-2020 11:04:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYF8Y	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jul-15-2020 11:04:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYF8Y	Initial Entry

5.h

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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

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Site No: 1003

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Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-15-2020 11:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYF8Z	Initial Entry
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5.h Sample ID

Date	Location	User	Value	Reason
Jul-15-2020 11:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYF8Z	Initial Entry

5.i

Date	Location	User	Value	Reason
Jul-15-2020 11:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYF90	Initial Entry

5.i Sample ID

Date	Location	User	Value	Reason
Jul-15-2020 11:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYF90	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jul-15-2020 11:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jul-15-2020 11:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jul-15-2020 11:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jul-15-2020 11:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jul/15/2020 09:46	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jul-15-2020 11:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jul-15-2020 11:54:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jul-15-2020 11:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jul-15-2020 11:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 0.5	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jul-15-2020 11:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: mL	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jul-15-2020 11:53:35 (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
Jul-15-2020 11:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: YES	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Jul-22-2020 12:48:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jul/22/2020	Initial Entry

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Exam Date:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Jul/22/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examined: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: GENERAL APPEARANCE	Initial Entry

2.a Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examined: SKIN Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: SKIN	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined HEAD : Result: NORMA L	Initial Entry

2.c Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: HEAD	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined EYES : Result: NORMA L	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NORMAL	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examine EARS d: Result: NOT DON E	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: EARS	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NOT DONE	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examine NOSE d: Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOSE	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine THROAT d: Result: NOT DON E	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: THROAT	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine HEART d: Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: HEART	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine LUNGS d: Result: NOT DON E	Initial Entry

2.i Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine ABDOME d: N Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.k

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: MUSCULOSKELETAL Result: NORMAL	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: MUSCULOSKELETAL	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: EXTREMITIES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: EXTREMITIES	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: NEUROLOGICAL Result: NORMAL	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NEUROLOGICAL	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.n

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: LYMPH NODES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LYMPH NODES	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jul-22-2020 12:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

Header Text: c4591001**Visit:** V5_WEEK1_POSTVAX2_S**Form Version:** 17-Jul-2020 21:54**Site No:** 1003**Subject No:** 10031065**Generated By:** pfe.levissc**Form:** VITAL SIGNS - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jul-22-2020 12:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jul/22/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-22-2020 12:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Record Identifier:: 1 Temperature: 98.6 Temperature Unit: F Temperature Location:: FOREHEAD Systolic: 103 Diastolic: 63 BP Position: SITTING Pulse:: 69	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: 98.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: F	Initial Entry

2.a Temperature Location:

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Jul-22-2020 12:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> FOREHEAD	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> 103	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> 63	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> 69	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** V5_WEEK1_POSTVAX2_S**Form Version:** 17-Jul-2020 21:53**Site No:** 1003**Subject No:** 10031065**Generated By:** pfe.levissc**Form:** CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Collection Date:**

Date	Location	User	Value	Reason
Jul-22-2020 12:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jul/22/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jul-22-2020 12:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Category for Lab Test: CLINICAL CHEMISTRY Subcategory for Lab Test: BLOOD CHEMISTRY Lab Sub-Panel C collected: YES	Initial Entry

3.a Lab Panel:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: BLOOD CHEMISTRY	Initial Entry

3.a Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:39	ACV0PFEINFP6000	Mary Criddle	Data Entry:	Initial Entry

Header Text: c4591001
Visit: V5_WEEK1_POSTVAX2_S **Form:** CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History
Form Version: 17-Jul-2020 21:53 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital
Subject No: 10031065 **Subject Initials:** ---
Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)		(pfe mcriddle)	YES	
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3.b

Date	Location	User	Value	Reason
Jul-22-2020 12:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Category for Lab Test: HEMATOLOGY Subcategory for Lab Test: DIFFERENTIAL Lab Sub-Panel Collected: YES	Initial Entry

3.b Lab Panel:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: HEMATOLOGY	Initial Entry

3.b Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: DIFFERENTIAL	Initial Entry

3.b Was the lab sub-panel collected?:

Date	Location	User	Value	Reason
Jul-22-2020 12:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: YES	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jul-22-2020 12:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-22-2020 12:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-22-2020 15:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-22-2020 12:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-22-2020 12:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: YES Date of Collection: Jul/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-22-2020 15:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJG6Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-22-2020 15:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJG6Z	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jul-22-2020 15:12:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJG70	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-22-2020 15:12:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJG70	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-22-2020 15:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJG71	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Jul-23-2020 11:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Cl osed	Auto closed by Validation Check: VC_BEETRK001_01
Jul-23-2020 09:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Query 1: A nswered	Original value is correct
Jul-22-2020 17:09:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: O pened	DMW4053121;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Jul-22-2020 15:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry : BGJG71	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-23-2020 09:57:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJG72	Transcription Error
Jul-22-2020 15:12:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJG71	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Jul-23-2020 11:15:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Jul-23-2020 09:57:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jul-23-2020 09:57:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry : BGJG72	Transcription Error
Jul-22-2020 17:09:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW4053122;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Jul-22-2020 15:12:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry : BGJG71	Initial Entry

5.e

Date	Location	User	Value	Reason
Jul-22-2020 15:12:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJG73	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jul-22-2020 15:12:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJG73	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

5.f

Date	Location	User	Value	Reason
Jul-22-2020 15:12:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BNYFG5	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Jul-22-2020 15:12:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BNYFG5	Initial Entry

5.g

Date	Location	User	Value	Reason
Jul-22-2020 15:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BNYFG6	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jul-22-2020 15:12:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BNYFG6	Initial Entry

5.h

Date	Location	User	Value	Reason
Jul-22-2020 15:12:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BNYFG7	Initial Entry

5.h Sample ID

Date	Location	User	Value	Reason
Jul-22-2020 15:12:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BNYFG7	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Jul-29-2020 10:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jul/29/2020	Initial Entry

Header Text: c4591001**Visit:** V6_WEEK2_POSTVAX2_S**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:54**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031065**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	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
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Symptom:: FAT IG UE	Initial Entry

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<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
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> <u>Symptom::</u> HEA DAC HE 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
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<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
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

2.d

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<u>Data Entry:</u> Symptom:: CHILL S 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
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	<u>Data Entry:</u> Symptom:: VO MITING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

2.e Symptom:

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<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
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> Symptom:: DIA RR HE A Were fever or systemic symp toms present on the last day the Subject Diary was compl eted?: NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<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
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19	ACV0PFEINFP6000	Mary Criddle	<u>Data Entry:</u>	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe mcriddle)	Symptom:: NEW OR WORSE ED MUSC LE PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	
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2.g Symptom:

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NEW OR WORSE NED MUSCLE P AIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Symptom:: NEW OR WORSE NED JOINT PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Symptom:

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (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
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the Su bject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: REDNESS	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** V6_WEEK2_POSTVAX2_S**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:54**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031065**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	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
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	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
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	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
Jul-29-2020 10:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Exam Date:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Jul/29/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examined: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: GENERAL APPEARANCE	Initial Entry

2.a Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examined: SKIN Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.b Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: SKIN	Initial Entry

2.b Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined HEAD : Result: NORMA L	Initial Entry

2.c Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: HEAD	Initial Entry

2.c Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined EYES : Result: NORMA L	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.d Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NORMAL	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examine EARS d: Result: NOT DON E	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: EARS	Initial Entry

2.e Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NOT DONE	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: Body System Examine NOSE d: Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

2.f Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOSE	Initial Entry

2.f Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine THROAT d: Result: NOT DON E	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: THROAT	Initial Entry

2.g Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine HEART d: Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.h Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: HEART	Initial Entry

2.h Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine LUNGS d: Result: NOT DON E	Initial Entry

2.i Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examine ABDOME d: N Result: NOT DON E	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.j Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.k

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: MUSCULOSKELETAL Result: NOT DONE	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: MUSCULOSKELETAL	Initial Entry

2.k Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: EXTREMITIES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: EXTREMITIES	Initial Entry

2.1 Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: NEUROLOGICAL Result: NOT DONE	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NEUROLOGICAL	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT DONE	Initial Entry

2.n

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Body System Examined: LYMPH NODES Result: NORMAL	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

2.n Body System Examined:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: LYMPH NODES	Initial Entry

2.n Result:

Date	Location	User	Value	Reason
Jul-29-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NORMAL	Initial Entry

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jul-29-2020 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jul/29/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-30-2020 07:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Record Identifier:: 1 Temperature: 99.1 Temperature Unit: F Temperature Location:: FOREHEAD Systolic:: 100 Diastolic:: 70 BP Position: SITTING Pulse:: 84	Transcription Error
Jul-29-2020 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Record Identifier:: 1 Temperature: 99.1 Temperature Unit: C Temperature Location:: FOREHEAD Systolic:: 100 Diastolic:: 70 BP Position: SITTING Pulse:: 84	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jul-29-2020 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Jul-29-2020 12:25:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Closed	Re-queried on Unit Item
Jul-29-2020 10:24:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	Original value is correct
Jul-29-2020 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 99.1 C is outside of Normal Range 36.1 - 37.5 C.
Jul-29-2020 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 99.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jul-31-2020 03:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sanjay Mishra (pfe.mishrs01)	Query 1: Closed	Response satisfies query
Jul-30-2020 07:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jul-30-2020 07:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: F	Transcription Error
Jul-30-2020 00:28:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sanjay Mishra (pfe.mishrs01)	Query 1: Reissued:Opened	Re- Query: Temperature 99.1 C is outside of Normal Range 36.1 - 37.5 C. Please review Unit it seems Temperature given in Fahrenheit and Unit provided in Celsius. Please confirm.
Jul-29-2020 15:37:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	Original value is correct
Jul-29-2020 12:25:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Opened	DM Query: Temperature 99.1 C is outside of Normal Range 36.1 - 37.5 C. Please review Unit and update

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form: VITAL SIGNS - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

				accordingly or clarify.
Jul-29-2020 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	<u>Data Entry:</u> C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jul-29-2020 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> FOREHEAD	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jul-29-2020 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> 100	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jul-29-2020 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> 70	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jul-29-2020 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
Jul-29-2020 10:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	<u>Data Entry:</u> 84	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jul-29-2020 10:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-29-2020 10:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-29-2020 15:03:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-29-2020 10:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-29-2020 10:20:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: YES Date of Collection: Jul/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-29-2020 15:03:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJWB4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-29-2020 15:03:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJWB4	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jul-29-2020 15:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJWB5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 15:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJWB5	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-29-2020 15:03:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJWB6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 15:03:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJWB6	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-29-2020 15:03:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BGJWB7	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 15:03:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BGJWB7	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

5.e

Date	Location	User	Value	Reason
Jul-29-2020 15:03:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BGJWB8	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 15:03:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BGJWB8	Initial Entry

5.f

Date	Location	User	Value	Reason
Jul-29-2020 15:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BNYFK6	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 15:14:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BNYFK6	Initial Entry

5.g

Date	Location	User	Value	Reason
Jul-29-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BNYFK7	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BNYFK7	Initial Entry

5.h

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-29-2020 15:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNYFK8	Initial Entry
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5.h Sample ID

Date	Location	User	Value	Reason
Jul-29-2020 15:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNYFK8	Initial Entry

Header Text: c4591001

Visit: V7_MONTH1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Aug-19-2020 10:43:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe mfrancis)	Data Entry: Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: V7_MONTH1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 10:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 10:43:54 (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-19-2020 11:59:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 10:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 10:43:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe mfrancis)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Aug-19-2020 12:00:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: low draw	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V7_MONTH1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-19-2020 11:59:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BP57GS	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 11:59:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BP57GS	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-19-2020 11:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BP57GT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 11:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BP57GT	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-19-2020 11:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BP57GV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 11:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BP57GV	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-19-2020 11:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BP57GW	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V7_MONTH1_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

5.d Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 11:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BP57GW	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-19-2020 11:59:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BP57GX	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 11:59:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BP57GX	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-19-2020 12:00:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BKDZ5T	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 12:00:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BKDZ5T	Initial Entry

5.g

Date	Location	User	Value	Reason
Aug-19-2020 12:00:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BKDZ5V	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V7_MONTH1_S

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

5.g Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 12:00:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BKDZ5V	Initial Entry

Header Text: c4591001

Visit: V8_MONTH6_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Jan-08-2021 14:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jan/8/2021	Initial Entry

Header Text: c4591001

Visit: V8_MONTH6_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-08-2021 14:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-08-2021 14:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-08-2021 15:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 14:43:38 (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.
Jan-08-2021 14:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Collection: Jan/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-08-2021 15:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BPYLH4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8_MONTH6_S

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Jan-08-2021 15:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BPYLH4	Initial Entry
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5.b

Date	Location	User	Value	Reason
Jan-08-2021 15:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNWKSX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-08-2021 15:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNWKSX	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-08-2021 15:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BNWKSX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-08-2021 15:11:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BNWKSX	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 10:41:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Mar/3/2021	Initial Entry

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:11

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: INFORMED CONSENT - BOOSTER - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Mar-03-2021 10:41:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Mar/3/2021	Initial Entry

Header Text: c4591001

Visit: V8A_VAX3

Form: DISPOSITION - SCREENING FOR BOOSTER DOSE - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:10

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-03-2021 10:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Mar/3/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-03-2021 10:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 2	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-03-2021 10:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:16

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Mar-03-2021 10:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Mar/3/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Mar-03-2021 10:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Mar-03-2021 10:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Mar-03-2021 10:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 97.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Mar-03-2021 10:43:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Mar-03-2021 10:43:32 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Megan Helf	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:16

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

(US & Canada)

(pfe.ahelf)

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Mar-03-2021 10:43:49 (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
Mar-03-2021 10:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-03-2021 10:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Mar/3/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Mar-03-2021 10:43:49 (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
Mar-03-2021 10:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-03-2021 10:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

			Result: NEGATIVE	
			Not Done:	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-03-2021 10:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-03-2021 10:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Mar-03-2021 10:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-03-2021 10:44:00 (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-03-2021 10:44:00 (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-03-2021 13:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 10:44:00 (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-03-2021 10:44:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 13:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BPYLTM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Mar-03-2021 13:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BPYLTM	Initial Entry
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5.b

Date	Location	User	Value	Reason
Mar-03-2021 13:20:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BVR36V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 13:20:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BVR36V	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-03-2021 13:20:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BVR36W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 13:20:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BVR36W	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-03-2021 10:45:44 (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-03-2021 10:45:44 (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
Mar-03-2021 13:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 10:45:44 (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-03-2021 10:45:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Collection: Mar/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 13:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: Sample ID: BPYLTK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

Mar-03-2021 13:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	Data Entry: BPYLTk	Initial Entry
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Header Text: c4591001

Visit: V8A_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-03-2021 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-03-2021 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-03-2021 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-03-2021 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Mar/3/2021 08:44	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-03-2021 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-03-2021 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: LEFT	Initial Entry

7. Route:

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Mar-03-2021 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-03-2021 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-03-2021 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-03-2021 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-03-2021 10:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8B_WEEK1_POSTVAX3

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 15:32:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Mar/10/2021	Initial Entry

Header Text: c4591001

Visit: V8B_WEEK1_POSTVAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-10-2021 15:34:08 (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-10-2021 15:34:08 (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-11-2021 10:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-11-2021 06:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-10-2021 15:34:08 (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-10-2021 15:34:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Collection: Mar/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-11-2021 10:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BPYLVT	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8B_WEEK1_POSTVAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 10:11:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BPYLVLT	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-11-2021 10:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BVR394	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 10:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BVR394	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-11-2021 10:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> Sample ID: BVR395	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 10:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe mmurphy)	<u>Data Entry:</u> BVR395	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Jul/16/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Jul-20-2020 14:12:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jul/16/2020	Transcription Error
Jul-17-2020 10:01:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschnegeburger)	Data Entry: Jul/17/2020	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Jul/16/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

I. Assessments

Date	Location	User	Value	Reason
Jul-17-2020 10:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-17-2020 10:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Jul-17-2020 10:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Jul/16/2020**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031065**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Jul-17-2020 10:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Jul-20-2020 14:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jul-20-2020 14:50:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: YES Date of Contact: Jul/16/2020 Contact Outcome: VISIT NOT REQUIRED, I NVESTIGATOR DECISIO N	Changed Information
Jul-20-2020 14:12:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Contact 17/Jul/2020 is not equal to the Date of Visit 16/Jul/2020 within same unplanned visit. Please review and update as appropriate.
Jul-17-2020 10:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: YES Date of Contact: Jul/17/2020 Contact Outcome: VISIT NOT REQUIRED, I NVESTIGATOR DECISIO	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Jul/16/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levisse

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

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3. Comments:

Date	Location	User	Value	Reason
Jul-21-2020 15:43:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora (pfe.signoj01)	Query 1: Closed	Response satisfies query
Jul-20-2020 15:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jul-20-2020 15:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Pt. Report: mild fever of (100.4 -101.1 degree F), mild pain at injection site, severe fatigue and moderate headache. PI determined no site visit is clinically needed.	Changed Information
Jul-20-2020 15:08:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora (pfe.signoj01)	Query 1: Opened	DM QUERY: A carriage return 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).
Jul-17-2020 10:07:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: Pt report: mild fever of (100.4-101.1 degree F), mild pain at injection site, severe fatigue, and moderate headache. PI determined no site visit is clinically needed.	Changed Information
Jul-17-2020 10:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: PI determined no site visit is clinically necessary for the subject's reported symptoms.	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 22-Apr-2020 21:05**Site No:** 1003**Subject No:** 10031065**Generated By:** pfe.levissc**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Aug-21-2020 08:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe noig)	Query 1: Closed	Response satisfies query
Aug-21-2020 08:30:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-21-2020 08:30:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Aug/19/2020	Changed Information
Aug-21-2020 07:09:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Opened	DM Query : Date of visit 7 is 19Aug2020, however, Date of visit on EOT is 15Jul2020. Please review and update the data as appropriate.
Aug-20-2020 10:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jul/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-20-2020 10:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-20-2020 10:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Form Created	

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Oct-28-2020 11:30:54 (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
Oct-28-2020 11:30:54 (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
Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: right arm pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: Jul/29/2020 09:40	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-02-2020 11:51:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samantha Malkowski (pfe malkos)	Query 1: Closed	Response satisfies query
Nov-02-2020 11:04:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-02-2020 11:04:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: YES	New Information
Oct-29-2020 10:48:01 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Samantha Malkowski	Query 1: Opened	Please confirm if this is still ongoing,

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (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, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

(US & Canada)		(pfe malkos)		thanks!
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-03-2020 01:40:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 2: Closed	Response satisfies query
Nov-02-2020 18:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-02-2020 18:20:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER	Changed Information

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1003**Subject No:** 10031065**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

			<i>If Other, specify:</i> unknown	
Nov-02-2020 15:42:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe noig)	Query 2: Opened	DM: The question "If Not Related to study treatment(s), this event is due to:" is not completed. Please review and update accordingly.
Nov-02-2020 15:31:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samantha Malkowski (pfe malkos)	Query 1: Closed	Response satisfies query
Nov-02-2020 14:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Nov-02-2020 14:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT RELATED	New Information
Oct-29-2020 10:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Samantha Malkowski (pfe malkos)	Query 1: Opened	Please confirm if this is related to study treatment, thanks!

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 11:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcriddle)	Data Entry: NO	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-12-2020 15:00:11 (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
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-25-2021 15:27:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Closing query on a deleted AE
Feb-18-2021 13:53:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	New Information
Feb-18-2021 13:53:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: neuritis	New Information
Feb-17-2021 16:40:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical Event term is Peripheral Nerve Injury; however, event term on most recent SAE (#2020449114) update was changed to Neuritis. Please review, harmonize reporting, and update where applicable
Feb-17-2021 16:38:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Feb-05-2021 09:38:37 (UTC-05:00) Eastern	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 3: Answered	SAE Safety F/U for EMG and nerve

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1003**Subject No:** 10031065**Generated By:** pfe.lewissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Not Complete**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Time (US & Canada)				conduction study results sent. no abnormalities and noted SAE is still ongoing
Feb-01-2021 19:49:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical - Followup Please submit a SAE safety followup with EMG & Nerve conduction study results/Neuro followup, if available; also event end date if occurred.
Dec-15-2020 12:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Dec-14-2020 07:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Query 2: Answered	Patient has follow-up in January. No new information available.
Dec-07-2020 18:21:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Please submit a SAE safety followup with EMG results/Neuro followup, if available; also event end date if occurred.
Nov-30-2020 09:29:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe noig)	Query 1: Closed	Response satisfies query
Nov-30-2020 07:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-30-2020 07:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: peripheral nerve injury	Transcription Error
Nov-27-2020 06:41:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020449114, the term was updated to 'peripheral nerve injury' in Safety database while recorded as 'ritis right arm' in AE CRF. Please confirm correct term. If safety update is required, please submit

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, Not Complete

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

				a follow-up form.
Nov-12-2020 15:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: neuritis right arm	New Information
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: neuritis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jul/29/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 08:55:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	Response satisfies query
Mar-05-2021 08:54:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	AE is ongoing appointment with vascular pending
Mar-04-2021 16:08:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clinical: pls confirm AE ongoing or update end date in CRF. Thanks
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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
Nov-13-2020 07:14:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-12-2020 15:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE neuritis right arm: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE neuritis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	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? NO Did this serious event result in persistent or significant disability/incapacity? YES Is this serious event life threatening? NO	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-13-2020 12:10:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe noig)	Query 1: Closed	Response satisfies query
Nov-13-2020 11:22:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-13-2020 11:22:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> related to study blood draw	Changed Information
Nov-13-2020 07:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020449114 ,causality was recorded as UNRELATED in Safety database but was recorded as RELATED in AE CRF. Please confirm correct causality. If safety update is required, please submit a follow-up form.
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe mcridle)	Data Entry: RELATED	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Not Complete

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NOT RECOVERED/NOT RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Nov-12-2020 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-13-2020 07:14:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quiton)	Data Entry: 2020449114	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: UNPLANNED_BOOSTER_CONTACT -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Mar-03-2021 10:40:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Feb/11/2021	Initial Entry

Header Text: c4591001

Visit: UNPLANNED_BOOSTER_CONTACT -
Unscheduled

Form: BOOSTER DOSE TRIGGER FORM - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:20

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?

Date	Location	User	Value	Reason
Mar-03-2021 10:40:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: The participant will return for consent/ eligibility assessment for the booster d ose visit	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Jan-08-2021 14:44:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jan/8/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031065

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-19-2021 17:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry
Jan-08-2021 14:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry:	Transcription Error
Jan-08-2021 14:44:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-08-2021 14:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jan/8/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-08-2021 14:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Subject Status

Date	Location	User	Value	Reason
Aug-20-2020 10:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jun-24-2020 12:12:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jun-12-2020 13:26:08 (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
Mar-11-2021 13:36:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 1: Closed	Response satisfies query
Mar-11-2021 08:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	subject had no covid like symptoms and deemed erroneous
Mar-11-2021 01:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ajit Malode (pfe.maloda)	Query 1: Reissued:Opened	Illness eDiary Q1: Thank you for response, please confirm if Illness eDiary entry on 05Mar2021 was deemed erroneous and that subject had no COVID Illness related symptoms. Else clarify.
Mar-10-2021 15:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	DCF out to change this from yes to no
Mar-10-2021 14:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031065

Generated By: pfe.lewissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

				the COVID-19 symptoms or diagnosis on 05Mar2021. But there is no COVID Illness visit reported in the database. Please clarify.
Aug-21-2020 08:30:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Changed Information
Aug-20-2020 10:12:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/15/2020	Initial Entry
Jun-24-2020 12:12:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jun/24/2020	Initial Entry
Jun-12-2020 13:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jun/12/2020	Initial Entry

090177e196ae3d68\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031065

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Aug-24-2020 21:20:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Edward Walsh (pfe.ewalsh)	Data Entry: Click Here to Enable	Initial Entry