

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 19-May-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	13 MAY 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 1 SENTINEL COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jun/5/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10031038]
2.	Birth Date:	(b) (6)/1967
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

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Visit: SCR

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

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/5/2020
2.	Erroneous Visit	

Header Text: c4591001**Visit:** SCR**Form Version:** 19-May-2020 00:47**Site No:** 1003**Subject No:** 10031038**Generated By:** pfe.lewissc**Form:** INCLUSION/EXCLUSION CRITERIA**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**

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

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Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA

Form Version: 19-May-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

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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

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

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Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

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	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

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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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

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Site No: 1003

Subject No: 10031038

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Form: INCLUSION/EXCLUSION CRITERIA

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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2.1	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
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

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Form: INCLUSION/EXCLUSION CRITERIA

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

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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

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Header Text: c4591001

Visit: SCR

Form Version: 19-May-2020 00:47

Site No: 1003

Subject No: 10031038

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

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.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

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Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031038

Generated By: pfe.lewissc

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/5/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031038

Generated By: pfe.lewissc

Form: GENERAL MEDICAL 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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Elevated Cholesterol]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Lower Back Pain]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Groin Pain]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

Form: GENERAL MEDICAL 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

1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hernia Surgery]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Penicillin Allergy]
	Start Date:	UNK/UNK/1972
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hernia Injury]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017

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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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Header Text: c4591001

Visit: SCR

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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

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[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

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jun/5/2020
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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

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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2.i	Body System Examined:	LUNGS
	Result:	NORMAL
2.j	Body System Examined:	ABDOMEN
	Result:	NORMAL
2.k	Body System Examined:	MUSCULOSKELETAL
	Result:	NORMAL
2.l	Body System Examined:	EXTREMITIES
	Result:	NORMAL
2.m	Body System Examined:	NEUROLOGICAL
	Result:	NORMAL
2.n	Body System Examined:	LYMPH NODES
	Result:	NORMAL

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jun/5/2020
2.	Weight:	[169.0]
3.	Unit:	LB
4.	Height:	[69.5]
5.	Unit:	in
6.	Body Mass Index:	[24.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[138]
	Diastolic:	[88]
	BP Position:	SITTING
	Pulse:	[64]

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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: 10031038

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/5/2020
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	[BNBTN1]
5.b	Sample ID	[BNBTN2]
5.c	Sample ID	[BNYG0J]

090177e196ae3d67\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: 10031038

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/5/2020	BLOOD	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	NEGATIVE	Repeating Pages

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Header Text: c4591001

Visit: SCR

Form: MICROBIOLOGY SPECIMEN

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: 10031038

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Generated By: pfe.levissc

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

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Jun/5/2020
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:	[]

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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: 10031038

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Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Central Lab Sample Collection

1.	Collection Date:	Jun/5/2020
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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

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/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: PHYSICAL EXAMINATION

Form Version: 12-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jun/17/2020
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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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.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
2.l	Body System Examined:	EXTREMITIES
	Result:	NOT DONE
2.m	Body System Examined:	NEUROLOGICAL
	Result:	NOT DONE
2.n	Body System Examined:	LYMPH NODES
	Result:	NOT DONE

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: VITAL SIGNS

Form Version: 12-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jun/17/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[96.9]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[143]
	Diastolic:	[85]
	BP Position:	SITTING
	Pulse:	[57]

090177e196ae3d67\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: 10031038

Generated By: pfe.levissc

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/17/2020
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	[BNBTXF]
-----	-----------	----------

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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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/17/2020	SWABBED MATERIAL	NASAL CAVITY	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae3d67\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 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital
Subject No: 10031038 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

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[Form Audit Trail](#)

Microbiology Specimen		
1.	Actual Date of Collection:	Jun/17/2020
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 XPERT XPRESS SARS-COV-2 TEST
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]

090177e196ae3d67\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: 10031038

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/17/2020
2.	Randomization Number:	[2574]
3.	Randomization Group:	[Stage 1, Age 18 to 55, Low-Mid dose level (20mcg), 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: 10031038

Generated By: pfe.levissc

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	Low-Mid dose level (20mcg)
4.	Select appropriate response - Randomization Dose Group	21 Day
5.	Select appropriate response - BNT Number	(BNT162b2 or PBO)

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Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 10031038

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/17/2020
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	[BNBTW1]
5.b	Sample ID	[BNBTW2]
5.c	Sample ID	[BNBTW3]
5.d	Sample ID	[BNBTW4]
5.e	Sample ID	[BNBTW5]
5.f	Sample ID	[BNYG48]
5.g	Sample ID	[BNYG49]
5.h	Sample ID	[BNYG4B]
5.i	Sample ID	[BNYG4C]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031038

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	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jun/17/2020 11:24
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

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Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

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/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: PHYSICAL EXAMINATION

Form Version: 12-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jun/19/2020
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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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.lewissc

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/19/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[148]
	Diastolic:	[76]
	BP Position:	SITTING
	Pulse:	[60]

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:47

Site No: 1003

Subject No: 10031038

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/19/2020
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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10031038

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	Jun/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_WEEK1_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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jun/24/2020
----	------------	-------------

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:	NOT DONE
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

090177e196ae3d67\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: 10031038

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

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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:	[97.2]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[133]
	Diastolic:	[76]
	BP Position:	SITTING
	Pulse:	[68]

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: CENTRAL LAB SAMPLE COLLECTION

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Central Lab Sample Collection

1.	Collection Date:	Jun/24/2020
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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 10031038

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/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	[BN8F8D]
5.b	Sample ID	[BN8F8F]
5.c	Sample ID	[BN8F8G]
5.d	Sample ID	[BN8F8H]
5.e	Sample ID	[BN8F8J]
5.f	Sample ID	[BNYFLN]
5.g	Sample ID	[BNYFLP]
5.h	Sample ID	[BNYFLR]
5.i	Sample ID	[BNYFLS]

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10031038

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/8/2020
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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jul/8/2020
----	------------	------------

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:	NORMAL
2.g	Body System Examined:	THROAT
	Result:	NORMAL
2.h	Body System Examined:	HEART
	Result:	NORMAL

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VITAL SIGNS

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/8/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[149]
	Diastolic:	[82]
	BP Position:	SITTING
	Pulse:	[68]

090177e196ae3d67\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: 10031038

Generated By: pfe.levissc

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/8/2020
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	[BN8D64]
-----	-----------	----------

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

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/8/2020	SWABBED MATERIAL	NASAL CAVITY	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 22-Apr-2020 21:05

Site No: 1003

Subject No: 10031038

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

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Jul/8/2020
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 XPERT XPRESS SARS-COV-2 TEST
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:52

Site No: 1003

Subject No: 10031038

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/8/2020
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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** V4_WEEK3_VAX2_S**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**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:** 10031038**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/8/2020
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	[BN8D59]
5.b	Sample ID	[BN8D5B]
5.c	Sample ID	[BN8D5C]
5.d	Sample ID	[BN8D5D]
5.e	Sample ID	[BN8D5F]
5.f	Sample ID	[BNYFVC]
5.g	Sample ID	[BNYFVD]
5.h	Sample ID	[BNYFVF]
5.i	Sample ID	[BNYFVG]

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form: VACCINATION

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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/8/2020 09:50
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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

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: 10031038

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/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jul/14/2020
----	------------	-------------

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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: VITAL SIGNS

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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/14/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.0]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[142]
	Diastolic:	[86]
	BP Position:	SITTING
	Pulse:	[59]

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form: CENTRAL LAB SAMPLE COLLECTION

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Central Lab Sample Collection

1.	Collection Date:	Jul/14/2020
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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** V5_WEEK1_POSTVAX2_S**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**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:** 10031038**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: Jul/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN8DBH]
5.b	Sample ID	[BN8DBJ]
5.c	Sample ID	[BN8DBK]
5.d	Sample ID	[BN8DBL]
5.e	Sample ID	[BN8DBM]
5.f	Sample ID	[BNYFZ3]
5.g	Sample ID	[BNYFZ4]
5.h	Sample ID	[BNYFZ5]
5.i	Sample ID	[BNYFZ6]

Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

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: 10031038

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/20/2020
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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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 WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
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

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Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

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

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Header Text: c4591001

Visit: 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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Physical Examination

1.	Exam Date:	Jul/20/2020
----	------------	-------------

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

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/20/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	FOREHEAD
	Systolic:	[153]
	Diastolic:	[87]
	BP Position:	SITTING
	Pulse:	[58]

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** V6_WEEK2_POSTVAX2_S**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**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:** 10031038**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: Jul/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BGJG3T]
5.b	Sample ID	[BGJG3V]
5.c	Sample ID	[BGJG3W]
5.d	Sample ID	[BGJG3X]
5.e	Sample ID	[BGJG3Y]
5.f	Sample ID	[BNYFD7]
5.g	Sample ID	[BNYFD8]
5.h	Sample ID	[BNYFDC]
5.i	Sample ID	[BNYFDD]

Header Text: c4591001

Visit: V7_MONTH1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

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/11/2020
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V7_MONTH1_S**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**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:** 10031038**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04**eCRF Audit Trail History****Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/11/2020
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	[BP578L]
5.b	Sample ID	[BP578M]
5.c	Sample ID	[BP578N]
5.d	Sample ID	[BP578P]
5.e	Sample ID	[BP578R]
5.f	Sample ID	[BKDZ3F]
5.g	Sample ID	[BKDZ3G]
5.h	Sample ID	[BKDZ3H]

Header Text: c4591001

Visit: V8_MONTH6_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

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	Dec/30/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V8_MONTH6_S

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 10031038

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: Dec/30/2020
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	[BPYLF9]
5.b	Sample ID	[BNWKPP]
5.c	Sample ID	[BNWKPR]

090177e196ae3d67\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: 10031038

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	Feb/25/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:11

Site No: 1003

Subject No: 10031038

Generated By: pfe.levissc

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 Feb/25/2021
----	--------------	--

Header Text: c4591001

Visit: V8A_VAX3

Form Version: 20-Feb-2021 02:11

Site No: 1003

Subject No: 10031038

Generated By: pfe.lewissc

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: 10031038

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 :	Feb/25/2021
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: 10031038

Generated By: pfe.lewissc

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:	Feb/25/2021
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[96.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 10031038

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: Feb/25/2021
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	[BPYLS3]
5.b	Sample ID	[BVR34V]
5.c	Sample ID	[BVR34W]

090177e196ae3d67\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: 10031038

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: Feb/25/2021
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	[BPYLRX]
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090177e196ae3d67\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: 10031038

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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/25/2021 09:50
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

090177e196ae3d67\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: 10031038

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/4/2021
2.	Erroneous Visit	

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8B_WEEK1_POSTVAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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: 10031038

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: Mar/4/2021
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	[BPYLV6]
5.b	Sample ID	[BVR37Z]
5.c	Sample ID	[BVR380]

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8C_MONTH1_POSTVAX3

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: 10031038

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: V8C_MONTH1_POSTVAX3

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: 10031038

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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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

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?	

090177e196ae3d67\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: 10031038

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: 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: 10031038

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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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V10_MONTH24_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

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: 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: 10031038

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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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General
Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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: 10031038

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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031038

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

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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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General
Hospital

Subject No: 10031038

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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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General
Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3d67\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: 10031038

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031038

Generated By: pfe.lewissc

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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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Aug/11/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB -
New 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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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: 10031038

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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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

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	appendicitis	Sep/19/2020 UNK:UNK	NO End Date Time: Sep/23/2020 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[appendicitis]
4.	Start Date Time:	Sep/19/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/23/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001		Form: ADVERSE EVENT REPORT	
Visit: Logs - Unscheduled		Form Status: Data Complete, Frozen	
Form Version: 22-Apr-2020 21:02		Site Name: (1003) Rochester Regional HealthRochester General Hospital	
Site No: 1003		Subject Initials: ---	
Subject No: 10031038		Generated Time (GMT): 29-Mar-2021 04:04	
Generated By: pfe.levissc			
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: [appendicitis]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	YES	Comments
12.	Was a Non-Drug Treatment given?	YES	
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED	
14.	Did the adverse event cause the subject to be discontinued from the study?	NO	
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021001152]	

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1003

Subject No: 10031038

Generated By: pfe.levissc

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	[]

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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Concomitant Medications

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

090177e196ae3d67\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: 10031038

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

090177e196ae3d67\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: 10031038

Generated By: pfe.levissc

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?	

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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: 10031038

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: 10031038

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: 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: 10031038

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?	

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General
Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General
Hospital

Subject No: 10031038

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	Dec/30/2020
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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/30/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: 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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Aug/11/2020

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE -
Comments

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Jun-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No Current medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE -
Comments

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
1	Jun-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No Current medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE -
Comments

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
2	Jun-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No Current medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE -
Comments

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
3	Jun-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No Current medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE -
Comments

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
4	Jun-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No Current medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE -
Comments

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
5	Jun-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No Current medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE -
Comments

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
6	Jun-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No Current medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE -
Comments

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
7	Jun-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No Current medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE -
Comments

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
8	Jun-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No Current medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: SCR

Form: CONCOMITANT MEDICATIONS - BASELINE -
Comments

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
9	Jun-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	No Current medications at this time <hr/> Not Applicable

Header Text: c4591001

Visit: V8A_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - BOOSTER -
Comments

Form Version: 20-Feb-2021 02:11

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General
Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
Form	Mar-11-2021 11:12:20 (UTC-05:00) Eastern Time (US & Canada)	Megan Helf (pfe.ahelf)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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Item	Date	User	Comment
11	Jan-20-2021 10:50:15 (UTC-05:00) Eastern Time (US & Canada)	Mary Criddle (pfe.mcriddle)	not known what type of antibiotic given. not listed in brief after visit summary from hospital.

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Lauren Mitchell	N/A	Dec-30-2020 07:53:49 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Edward Walsh	Approved	Aug-24-2020 20:56:58 (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.

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 19-May-2020 00:47

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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-05-2020 12:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: 13 MAY 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jun-05-2020 12:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: STAGE 1 SENTINEL CO HORTS	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - 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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Consent Was:

Date	Location	User	Value	Reason
Jun-10-2020 07:57:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: OBTAINED Date Written Consent Obtai ned Jun/5/2020	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Subject ID

Date	Location	User	Value	Reason
Jun-05-2020 12:08:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10031038	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jun-05-2020 12:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1967	Screening Log Entry

3. Sex:

Date	Location	User	Value	Reason
Jun-15-2020 15:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Josee Robillard (pfe.robilj01)	Query 1: Closed	MALE both in InForm and Impala
Jun-10-2020 09:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	After checking subject information in Impala for 10031038 subject gender is reported as male. This matches what gender is reported in inform.
Jun-10-2020 09:22:57	ACV0PFEINFP6000	Jeffrey Signora	Query 1: Opened	DM QUERY: There is a

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-05:00) Eastern Time (US & Canada)		(pfe.signoj01)		mismatch between the sex reported in InForm and the sex report in IMPALA. Please review and reconcile.
Jun-10-2020 07:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jun-10-2020 07:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: WHITE	Initial Entry

090177e196ae3d67\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: 10031038

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jun-10-2020 07:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/5/2020	Initial Entry

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 19-May-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1.a

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<p>Data Entry:</p> <p>Inclusion Number:</p> <p>Criterion: 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)</p> <p>Criterion met? :</p> <p>Criterion ID: (For Pfizer only): IN01A00</p>	Initial Entry

1.a Inclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	Megan Helf	<p>Data Entry:</p> <p>1</p>	Initial Entry

Header Text: c4591001**Visit:** SCR**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 19-May-2020 00:47**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031038**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

Time (US & Canada)

(pfe.ahelf)

1.a Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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

1.a Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Inclus 2 ion N umbe r:	Initial Entry

Header Text: c4591001

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			<p>Crite Participants who are rion willing and able to co Descr mply with all schedul ption ed visits, vaccination : plan, laboratory tests, lifestyle consideratio ns, and other study pr ocedures</p> <p>Crite YES rion met?:</p> <p>Crite IN02A00 rion I D: (F or Pfi zer us e only):</p>	
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Header Text: c4591001**Visit:** SCR**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 19-May-2020 00:47**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031038**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04***1.b Inclusion Number:***

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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

1.b Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: IN02A00	Initial Entry

1.c

Date	Location	User	Value	Reason
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Header Text: c4591001

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

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<p>Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Megan Helf (pfe.ahelf)</p>	<p>Data Entry: 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)</p>	<p>Initial Entry</p>
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Header Text: c4591001**Visit:** SCR**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 19-May-2020 00:47**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031038**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04***1.c Inclusion Number:***

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 3	Initial Entry

1.c Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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

1.c Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: IN03A00	Initial Entry

1.d

Date	Location	User	Value	Reason
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Header Text: c4591001

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<p>Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Megan Helf (pfe.ahelf)</p>	<p>Data Entry: Inclus 4 ion N umbe r: Crite Capable of giving pe riion rsonal signed inform Descr ed consent, which in iption cludes compliance w : ith the requirements and restrictions listed in the ICD and in this protocol Crite YES riion met?: Crite IN04A00 riion I D: (F or Pfi zer us e only):</p>	<p>Initial Entry</p>
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Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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

1.d Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
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Header Text: c4591001

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

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Subject Initials: ---

Generated By: pfe.levissc

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Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclu 1 sion Num ber: Crite Other medical or psy ri chiatric condition inc Descr l. recent (within past ption year) or active suicid : al ideation/behavior/l ab abnormality that may increase the risk of study participation Crite NO ri met?: Crite EX01A00 ri D: (F or Pfi zer us e only):	Initial Entry
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Other medical or psychiatric condition incl. recent (within	Initial Entry

Header Text: c4591001

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

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Subject Initials: ---

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			past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	
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2.a Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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)

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: Criterion Description: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) Criterion met?: NO	Initial Entry

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Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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			Criteria ID: EX02A00 (For Pfizer use only)	
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2.b Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX02A00	Initial Entry

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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2.c

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<p>Data Entry:</p> <p>Exclusion Number:</p> <p>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)</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX03A00</p> <p>D: (For Pfizer use only):</p>	Initial Entry

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Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
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Header Text: c4591001

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Subject Initials: ---

Generated By: pfe.levisse

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Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<p>Data Entry:</p> <p>Exclusion Number: 4</p> <p>Criterion Description: Receipt of medications intended to prevent COV ID-19</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX04A00</p> <p>D: (For Pfizer use only):</p>	Initial Entry
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Header Text: c4591001**Visit:** SCR**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 19-May-2020 00:47**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031038**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**2.d Exclusion Number:**

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Receipt of medications inten ded to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusio 5 n Num er:	Initial Entry

Header Text: c4591001

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Subject No: 10031038

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			<p>Criterion Description: Stages 1 and 2 only: Previous clinical or microbiological diagnosis of COVID-19</p> <p>Criterion met?: NO</p> <p>Criterion ID: (For Pfizer use only): EX05A00</p>	
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Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Stages 1 and 2 only: Previous clinical or microbiological di agnosis of COVID-19	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusi 6 on Nu mber:	Initial Entry

Header Text: c4591001

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Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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			<p>Criteria on Description: Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)</p> <p>Criteria met?: NO</p> <p>Criteria ID: EX06A01 (For Pfizer use only):</p>	
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Subject Initials: ---

Generated By: pfe.levisse

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2.f Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Sentinel participants in Stage 1 only: Individuals at high risk for severe COVID-19 (full details in protocol)	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Excl 7 usion	Initial Entry

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			<p>Number:</p> <p>Criterion: 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>Criterion met?</p> <p>Criterion ID: (For Pfizer only): EX07A00</p>	
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Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX07A00	Initial Entry

2.h

Date	Location	User	Value	Reason
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Header Text: c4591001

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

<p>Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Megan Helf (pfe.ahelf)</p>	<p>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: EX08A00 (For Pfizer use only):</p>	<p>Initial Entry</p>
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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

2.h Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 8	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EX08A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	Megan Helf	<u>Data Entry:</u> Exclusi 9	Initial Entry

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Subject No: 10031038

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Subject Initials: ---

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

Time (US & Canada)		(pfe.ahelf)	<p>on Nu mber:</p> <p>Criteria Individuals with a h on Des istory of autoimmun criptio e disease or an activ n: e autoimmune disea se requiring therape utic intervention</p> <p>Criteria NO on met ?:</p> <p>Criteria EX09A00 on ID: (For Pf izer us e only) :</p>	
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Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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2.i Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 9	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX09A00	Initial Entry

2.j

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclu 10 sion	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX10A00	Initial Entry

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2.k

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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: EX11A00 D: (For Pfizer use only) :	Initial Entry

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2.k Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 11	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Women who are pregnant or breastfeeding	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EX11A00	Initial Entry

2.l

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Exclusion Number: 12	Initial Entry

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Subject No: 10031038

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			Criterion Description: Previous vaccination with any coronavirus vaccine	
			Criterion met?: NO	
			Criterion ID: (For Pfizer use only): EX12A00	

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Subject No: 10031038

Subject Initials: ---

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

2.1 Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX12A00	Initial Entry

2.m

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Exclusion Number: 13	Initial Entry

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Subject No: 10031038

Subject Initials: ---

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			<p>Criteria on Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids</p> <p>Criteria on met?: NO</p> <p>Criteria ID: (For Pfizer use only): EX13A01</p>	
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Subject Initials: ---

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2.m Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 13	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EX13A01	Initial Entry

2.n

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	Megan Helf	<u>Data Entry:</u> Exclusi 14	Initial Entry

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Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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Time (US & Canada)		(pfe.ahelf)	on Number: Criterion Description: Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids Criterion met?: Criterion ID: (For Pfizer use only): EX22A01	
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Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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2.n Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 14	Initial Entry

2.n Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Sentinel participants in Stage 1 only: Regular receipt of inhaled/nebulized corticosteroids	Initial Entry

2.n Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EX22A01	Initial Entry

2.o

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	Megan Helf	<u>Data Entry:</u> Exclu 15	Initial Entry

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Time (US & Canada)		(pfe.ahelf)	<p>CRITERION NUMBER:</p> <p>CRITERION DESCRIPTION: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study</p> <p>CRITERION MET?: NO</p> <p>CRITERION IDENTIFIER: EX14A01</p> <p>CRITERION TYPE: (Former Pfizer use only)</p>	
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2.o Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 15	Initial Entry

2.o Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EX14A01	Initial Entry

2.p

Date	Location	User	Value	Reason
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<p>Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACVOPFEINFP6000</p>	<p>Megan Helf (pfe.ahelf)</p>	<p>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?: Criterion ID: EX15A01 (For Pfizer use only):</p>	<p>Initial Entry</p>
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2.p Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 16	Initial Entry

2.p Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EX15A01	Initial Entry

2.q

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21	ACV0PFEINFP6000	Megan	<u>Data Entry:</u>	Initial Entry

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(UTC-05:00) Eastern Time (US & Canada)		Helf (pfe.ahelf)	<p>Exclusion Number: 17</p> <p>Criteria Description: Previous participation in other studies involving study intervention containing lipid nanoparticles</p> <p>Criteria met? NO</p> <p>Criteria ID: (For Pfizer use only): EX16A01</p>	
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2.q Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 17	Initial Entry

2.q Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.q Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EX16A01	Initial Entry

2.r

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	Megan Helf	<u>Data Entry:</u> Exclus 18	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 19-May-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)		(pfe.ahelf)	ion Nu mber: 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: EX17A01 Use only: (For Pfizer use only):	
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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 19-May-2020 00:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.r Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 18	Initial Entry

2.r Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EX17A01	Initial Entry

2.s

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21	ACV0PFEINFP6000	Megan	<u>Data Entry:</u>	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

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Site No: 1003

Subject No: 10031038

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

(UTC-05:00) Eastern Time (US & Canada)		Helf (pfe.ahelf)	<p>Excl 19 usio n Nu mber :</p> <p>Crite rion Desc ription: Sentinel participants i n Stage 1 only: Scree ning hematology/bloo d chemistry lab >=Gr ade 1 abnormality. Ex cept Bilirubin, other s table Grade1 abnorm alities may be conside red eligible by Investi gator</p> <p>Crite rion met? :</p> <p>Crite rion ID: (For Pfizer use only) :</p> <p>EX18A01</p>	
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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.s Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Sentinel participants in Stage 1 only: Screening hematology/blood chemistry lab >=Grade 1 abnormality. Except Bili rubin, other stable Grade1 abnormalities may be considered eligible by Investigator	Initial Entry

2.s Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX18A01	Initial Entry

2.t

Date	Location	User	Value	Reason
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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

<p>Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Megan Helf (pfe.ahelf)</p>	<p>Data Entry: 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? : Criterion ID: (For Pfizer use only) :</p>	<p>Initial Entry</p>
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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

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Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

2.t Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX19A01	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Form Version: 19-May-2020 00:47

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Site No: 1003

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Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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2.u

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<p>Data Entry:</p> <p>Exclusion Number:</p> <p>Criterion Description: Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention</p> <p>Criterion ID: NO</p> <p>Criterion ID: EX20A01</p> <p>Criterion ID: (For Pfizer use only):</p>	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.u Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 21	Initial Entry

2.u Criterion Description:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Sentinel participants in Stage 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention	Initial Entry

2.u Criterion met?

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EX20A01	Initial Entry

2.v

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21	ACV0PFEINFP6000	Megan	<u>Data Entry:</u>	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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

Helf (pfe.ahelf)

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: EX21A01 (For Pfizer use only)

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.v Exclusion Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (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-10-2020 07:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: EX21A01	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

Form: DISPOSITION - SCREENING - 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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jun-10-2020 07:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/5/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jun-10-2020 07:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d67\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:** 10031038**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Jun-10-2020 07:59:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 1 mber: Medical Histo Elevated Ch ry Term: olesterol Start Date: UNK/UNK/ 2014 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Jun-10-2020 07:59:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:59:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Elevated Cholesterol	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Jun-10-2020 07:59:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: UNK/UNK/2014	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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

1.a Ongoing:

Date	Location	User	Value	Reason
Jun-10-2020 07:59:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Jun-10-2020 07:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Chronic Lower Back Pain Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae3d67\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:** 10031038**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04***1.b Line/MH Number:***

Date	Location	User	Value	Reason
Jun-10-2020 07:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 07:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Chronic Lower Back Pain	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jun-10-2020 07:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: UNK/UNK/2018	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Jun-10-2020 07:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Jun-10-2020 08:00:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

			Medical History Term: Chronic Groin Pain Start Date: UNK/UNK/2018 Ongoing: YES	
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1.c Line/MH Number:

Date	Location	User	Value	Reason
Jun-10-2020 08:00:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 08:00:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Chronic Groin Pain	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Jun-10-2020 08:00:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: UNK/UNK/2018	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Jun-10-2020 08:00:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

1.d

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Header Text: c4591001

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Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-10-2020 08:00:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Hernia Surgery Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

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Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Jun-10-2020 08:00:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Jun-16-2020 11:48:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Closed	Response satisfies query
Jun-16-2020 09:25:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Query 1: Answered	Original value is correct
Jun-12-2020 10:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (pfe.hassaa38)	Query 1: Opened	Per CRF completion requirements section 8.6, please can the condition that led to the surgery/interventional procedure being carried out, be listed as a separate medical history entry. thanks
Jun-10-2020 08:00:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Hernia Surgery	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: SCR

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Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

1.d Start Date:

Date	Location	User	Value	Reason
Jun-10-2020 08:00:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: UNK/UNK/2017	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Jun-10-2020 08:00:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

1.e

Date	Location	User	Value	Reason
Jun-10-2020 09:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Line/MH Num 5 ber: Medical History Term: Penicillin Allergy Start Date: UNK/UNK/1972 Ongoing: YES	Transcription Error
Jun-10-2020 08:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 5 ber: Medical History Term: Penicillin Start Date: UNK/UNK/1972 Ongoing: YES	Initial Entry

Header Text: c4591001

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Subject Initials: ---

Generated By: pfe.levissc

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

1.e Line/MH Number:

Date	Location	User	Value	Reason
Jun-10-2020 08:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Jun-10-2020 10:38:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Jun-10-2020 09:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jun-10-2020 09:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry : Penicillin Allergy	Transcription Error
Jun-10-2020 08:43:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify PENICILLIN as follows.... Drug only reported. Are you reporting ALLERGY TO? INTERACTION

090177e196ae3d67\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:** 10031038**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

				WITH? Other? Please clarify and edit term. If reporting therapeutic use, please move the term to the appropriate medication module. Thank you.
Jun-10-2020 08:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Penicillin	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Jun-10-2020 08:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: UNK/UNK/1972	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Jun-10-2020 08:01:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Jun-16-2020 09:25:55	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

Header Text: c4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

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Subject Initials: ---

Generated By: pfe.levisse

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(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	Line/MH Number: 6 Medical History Term: hernia Injury Start Date: UNK/UNK/2017 Ongoing: NO End Date: UNK/UNK/2017	
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Header Text: c4591001

Visit: SCR

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

1.f Line/MH Number:

Date	Location	User	Value	Reason
Jun-16-2020 09:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Jun-16-2020 09:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: hernia Injury	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Jun-16-2020 09:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: UNK/UNK/2017	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Jun-16-2020 09:25:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

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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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Jun-10-2020 08:02:00 (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-10-2020 08:02:00 (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-10-2020 08:02:00 (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-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry

5. Dose:

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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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-10-2020 08:02:00 (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-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:00 (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-10-2020 08:02:00 (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-10-2020 08:02:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: SCR

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Exam Date:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/5/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examine d: Result: GENERAL APPEARANCE NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (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-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: SKIN Result: NORM AL	Initial Entry
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2.b Body System Examined:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (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-10-2020 08:02:55 (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-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: HEAD Result: NORM AL	Initial Entry

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Header Text: c4591001

Visit: SCR

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

2.c Body System Examined:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (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
Jun-10-2020 08:02:55 (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
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Body System Examined: EYES Result: NORMAL	Initial Entry

2.d Body System Examined:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NORMAL	Initial Entry

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Header Text: c4591001

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Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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2.e

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (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-10-2020 08:02:55 (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-10-2020 08:02:55 (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-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: NOSE Result: NORMAL	Initial Entry

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Header Text: c4591001

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Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

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-10-2020 08:02:55 (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
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NORMAL	Initial Entry

2.g

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Body System Examined: Result: THROAT NORMAL	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (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
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NORMAL	Initial Entry

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Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

2.h

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: HEART Result: NORMAL	Initial Entry

2.h Body System Examined:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (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-10-2020 08:02:55 (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-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: LUNGS Result: NORMAL	Initial Entry

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Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

2.i Body System Examined:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NORMAL	Initial Entry

2.j

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Body System Examined: ABDOMEN Result: NORMAL	Initial Entry

2.j Body System Examined:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NORMAL	Initial Entry

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Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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2.k

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: MUSCULOS KELETAL Result: NORMAL	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (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-10-2020 08:02:55 (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-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: EXTREM ITIES Result: NORMAL	Initial Entry

090177e196ae3d67\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: 10031038

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-10-2020 08:02:55 (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-10-2020 08:02:55 (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-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: NEUROLOGICAL Result: NORMAL	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (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-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

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Header Text: c4591001

Visit: SCR

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

2.n

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: LYMPH N ODES Result: NORMAL	Initial Entry

2.n Body System Examined:

Date	Location	User	Value	Reason
Jun-10-2020 08:02:55 (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-10-2020 08:02:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/5/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 169.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 69.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: in	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

6. Body Mass Index:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 24.6	Initial Entry

7.a

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Record Identifier: 1 Temperature: 97.6 Temperature Unit: F Temperature Location: FOREHEAD Systolic: 138 Diastolic: 88 BP Position: SITTING Pulse: 64	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 97.6	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

7.a Unit:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> FOREHEAD	Initial Entry

7.a Systolic:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 138	Initial Entry

7.a Diastolic:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> 88	Initial Entry

7.a BP Position:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> SITTING	Initial Entry

7.a Pulse:

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - 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-10-2020 08:03:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 64	Initial Entry

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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Jun-05-2020 12:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-05-2020 12:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-05-2020 12:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-05-2020 12:55:00 (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.
Jun-05-2020 12:55:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

			Jun/5/2020	
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5.a

Date	Location	User	Value	Reason
Jun-05-2020 12:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNBTN1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-05-2020 12:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNBTN1	Initial Entry

5.b

Date	Location	User	Value	Reason
Jun-05-2020 12:55:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNBTN2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jun-05-2020 12:55:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNBTN2	Initial Entry

5.c

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-05-2020 12:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYG0J	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jun-05-2020 12:55:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYG0J	Initial Entry

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Jun-10-2020 08:03:43 (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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/5/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:43 (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-10-2020 08:03:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

4. Device Type:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:43 (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-10-2020 08:03:43 (UTC-05:00) Eastern	ACV0PFEINFP6000	Megan Helf	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)

(pfe.ahelf)

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Collection Date:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jun/5/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jun-10-2020 08:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Category for CLINICAL Lab Test: CHEMISTR Y Subcategory BLOOD CH for Lab Test: EMISTRY Lab Sub-Pan YES el Collected:	Initial Entry

3.a Lab Panel:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:51 (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
Jun-10-2020 08:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

3.b

Date	Location	User	Value	Reason
Jun-10-2020 08:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Category for CLINICAL Lab Test: CHEMISTR Y Subcategory VIROLOGY for Lab Test: Lab Sub-Pan YES el Collected:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

3.b Lab Panel:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:51 (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-10-2020 08:03:51 (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-10-2020 08:03:51 (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-10-2020 08:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Category for Lab Test: HEMATOLOGY Subcategory for Lab Test: DIFFERENTIAL Lab Sub-Panel Collected: YES	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

3.c Lab Panel:

Date	Location	User	Value	Reason
Jun-10-2020 08:03:51 (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-10-2020 08:03:51 (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-10-2020 08:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jun-17-2020 10:37:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/17/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

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

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1. Exam Date:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examine d: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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

Jun-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NORM AL	Initial Entry
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2.b Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NORM AL	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

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.c Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: EYES Result: NORMAL	Initial Entry

2.d Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

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.e

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

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-17-2020 10:38:42 (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-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: THROAT Result: NOT DONE	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

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

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

2.h Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

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.i Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: ABDO MEN Result: NOT DONE	Initial Entry

2.j Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.k

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: MUSCULO SKELETAL Result: NOT DONE	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: EXTREM ITIES Result: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

2.m

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: NEUROL OGICAL Result: NOT DON E	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

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

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: LYMPH N ODES Result: NOT DONE	Initial Entry

2.n Body System Examined:

Date	Location	User	Value	Reason
Jun-17-2020 10:38:42 (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-17-2020 10:38:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.lewissc

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

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1. Date:

Date	Location	User	Value	Reason
Jun-17-2020 10:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-17-2020 10:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Record Identifier:: Temperature: 96.9 Temperature Unit: Temperature Location: FOREH Systolic:: 143 Diastolic:: 85 BP Position: SITTING Pulse:: 57	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jun-17-2020 10:39:28 (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
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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_S**Form Version:** 12-Jun-2020 21:48**Site No:** 1003**Subject No:** 10031038**Generated By:** pfe.levisse**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

Jun-18-2020 01:23:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 1: Closed	Response satisfies query
Jun-17-2020 10:41:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Query 1: Answered	Original value is correct
Jun-17-2020 10:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.9 F is outside of Normal Range 97 - 99.5 F.
Jun-17-2020 10:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 96.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jun-17-2020 10:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jun-17-2020 10:39:28 (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-18-2020 01:23:36	ACV0PFEINFP6000	Derrick Newton	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: V1_DAY1_VAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(pfe.newtod07)		
Jun-17-2020 10:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Query 1: Answered	Original value is correct
Jun-17-2020 10:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 143 is outside of Normal Range 90 - 140.
Jun-17-2020 10:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 143	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jun-17-2020 10:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 85	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jun-17-2020 10:39:28 (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-17-2020 10:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 57	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Jun-17-2020 09:54:19 (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-17-2020 09:54:19 (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-17-2020 09:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-17-2020 09:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jun-17-2020 09:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3d67\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: 10031038 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

			Jun/17/2020	
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<i>5.a</i>				
Date	Location	User	Value	Reason
Jun-17-2020 09:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNBTXF	Initial Entry

<i>5.a Sample ID</i>				
Date	Location	User	Value	Reason
Jun-17-2020 09:54:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNBTXF	Initial Entry

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Jun-17-2020 10:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jun-17-2020 10:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/17/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-17-2020 10:39:44 (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-17-2020 10:39:44 (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-17-2020 10:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jun-17-2020 10:39:44 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTI	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

Time (US & Canada)			C TEST	
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6. Trade Name:

Date	Location	User	Value	Reason
Jun-17-2020 10:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CEPHEID XPERT XPRESS SARS-COV-2 TEST	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jun-17-2020 10:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d67\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: 10031038

Generated By: pfe.lewissc

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Jun-17-2020 10:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jun-17-2020 10:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 2574	Initial Entry

3. Randomization Group:

Date	Location	User	Value	Reason
Jun-18-2020 16:56:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Stage 1, Age 18 to 55, Low-Mid dose level (20mcg), 21 Day (BNT162b2 or PBO)	Transcription Error
Jun-17-2020 10:40:41 (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

090177e196ae3d67\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: 10031038

Generated By: pfe.lewissc

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

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1. Select appropriate response - Randomization Stage

Date	Location	User	Value	Reason
Jun-17-2020 10:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Stage 1	Initial Entry

2. Select appropriate response - Randomization Age Group

Date	Location	User	Value	Reason
Jun-17-2020 10:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Age 18 to 55	Initial Entry

3. Select appropriate response - Randomization Dose

Date	Location	User	Value	Reason
Jul-01-2020 11:43:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora (pfe.signoj01)	Query 1: Closed	Response satisfies query
Jun-18-2020 16:56:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jun-18-2020 16:56:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Low-Mid dose level (20m cg)	Transcription Error
Jun-18-2020 13:25:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora (pfe.signoj01)	Query 1: Opened	IRT QUERY: Per IMPALA, subject's randomization dose is recorded

090177e196ae3d67\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: 10031038

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

				as low-mid dose level (20mcg). Please review and reconcile.
Jun-17-2020 10:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Medium dose level (30mcg)	Initial Entry

4. Select appropriate response - Randomization Dose Group

Date	Location	User	Value	Reason
Jun-17-2020 10:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 21 Day	Initial Entry

5. Select appropriate response - BNT Number

Date	Location	User	Value	Reason
Jun-17-2020 10:40:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: (BNT162b2 or PBO)	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Jun-17-2020 10:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-17-2020 10:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-17-2020 11:13:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-17-2020 10:40:54 (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.
Jun-17-2020 10:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES Date of Collection: Jun/17/2020	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

5.a

Date	Location	User	Value	Reason
Jun-17-2020 11:13:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNBTW1	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-17-2020 11:13:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNBTW1	Initial Entry

5.b

Date	Location	User	Value	Reason
Jun-17-2020 11:13:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNBTW2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jun-17-2020 11:13:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNBTW2	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-17-2020 11:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNBTW3	Initial Entry
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5.c Sample ID

Date	Location	User	Value	Reason
Jun-17-2020 11:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNBTW3	Initial Entry

5.d

Date	Location	User	Value	Reason
Jun-17-2020 11:13:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNBTW4	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jun-17-2020 11:13:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNBTW4	Initial Entry

5.e

Date	Location	User	Value	Reason
Jun-17-2020 11:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNBTW5	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

5.e Sample ID

Date	Location	User	Value	Reason
Jun-17-2020 11:13:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNBTW5	Initial Entry

5.f

Date	Location	User	Value	Reason
Jun-17-2020 11:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYG48	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Jun-17-2020 11:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYG48	Initial Entry

5.g

Date	Location	User	Value	Reason
Jun-17-2020 11:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYG49	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

5.g Sample ID

Date	Location	User	Value	Reason
Jun-17-2020 11:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYG49	Initial Entry

5.h

Date	Location	User	Value	Reason
Jun-17-2020 11:14:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYG4B	Initial Entry

5.h Sample ID

Date	Location	User	Value	Reason
Jun-17-2020 11:14:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYG4B	Initial Entry

5.i

Date	Location	User	Value	Reason
Jun-17-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYG4C	Initial Entry

090177e196ae3d67\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: 10031038

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.i Sample ID

Date	Location	User	Value	Reason
Jun-17-2020 11:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYG4C	Initial Entry

090177e196ae3d67\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: 10031038

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jun-17-2020 12:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jun-17-2020 12:32:25 (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-17-2020 12:32:25 (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-17-2020 12:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/17/2020 11:24	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jun-17-2020 12:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae3d67\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: 10031038

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

6. Body Side:

Date	Location	User	Value	Reason
Jun-17-2020 12:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jun-17-2020 12:32:25 (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-17-2020 12:32:25 (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-17-2020 12:32:25 (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-17-2020 12:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

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

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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-17-2020 12:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jun-19-2020 09:20:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jun/19/2020	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

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

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1. Exam Date:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jun/19/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examine: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: GENERAL APPEARANCE	Initial Entry

2.a Result:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NORMAL	Initial Entry

2.b

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examined: Result: NORM AL	Initial Entry

2.b Body System Examined:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (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-19-2020 09:22:12 (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-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examined: Result: NORM AL	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.c Body System Examined:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (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-19-2020 09:22:12 (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-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examined: EYES Result: NORMAL	Initial Entry

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Header Text: c4591001

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Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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-19-2020 09:22:12 (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-19-2020 09:22:12 (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-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examined: EARS Result: NOT DONE	Initial Entry

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Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.e Body System Examined:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (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-19-2020 09:22:12 (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-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Ex NOSE amed: Result: NOT D ONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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-19-2020 09:22:12 (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-19-2020 09:22:12 (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
Jun-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examined: THROAT T Result: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.g Body System Examined:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (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-19-2020 09:22:12 (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
Jun-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examined: HEART Result: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

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Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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-19-2020 09:22:12 (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-19-2020 09:22:12 (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
Jun-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examined: LUNGS Result: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.i Body System Examined:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (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-19-2020 09:22:12 (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
Jun-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examined: ABDO MEN Result: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

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.j Body System Examined:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (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-19-2020 09:22:12 (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
Jun-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examine d: MUSCULO SKELETAL Result: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.k Body System Examined:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (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-19-2020 09:22:12 (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-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examined: EXTREM ITIES Result: NORMA L	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.l Body System Examined:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: EXTREMITIES	Initial Entry

2.l Result:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (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-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System NEUROL Examined: OGICAL Result: NOT DON E	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.m Body System Examined:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:12 (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-19-2020 09:22:12 (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-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Body System Examined: LYMPH NODES Result: NORMA L	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

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-19-2020 09:22:12 (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-19-2020 09:22:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: NORMAL	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form Version: 12-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jun/19/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-19-2020 09:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Record Identifier:: Temperature: 98.0 Temperature U F nit: Temperature L FOREH ocation:: EAD Systolic:: 148 Diastolic:: 76 BP Position: SITTING Pulse:: 60	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 1	Initial Entry

2.a Temperature:

090177e196ae3d67\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: 12-Jun-2020 21:48

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-19-2020 09:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 98.0	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:59 (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-19-2020 14:02:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Josee Robillard (pfe.robilj01)	Query 1: Closed	Response satisfies query
Jun-19-2020 10:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	Original value is correct
Jun-19-2020 09:22:59 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 148 is outside of Normal Range

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: VITAL SIGNS - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)				90 - 140.
Jun-19-2020 09:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 148	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 76	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jun-19-2020 09:22:59 (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-19-2020 09:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: 60	Initial Entry

090177e196ae3d67\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:** 12-Jun-2020 21:47**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1003**Site Name:** (1003) Rochester Regional HealthRochester General Hospital**Subject No:** 10031038**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-19-2020 10:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jun/19/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-19-2020 10:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jun-19-2020 10:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Category fo CLINICAL r Lab Test: CHEMISTR Y Subcategor BLOOD CH y for Lab Te EMISTRY st: Lab Sub-Pa YES nel Collecte d:	Initial Entry

3.a Lab Panel:

Date	Location	User	Value	Reason
Jun-19-2020	ACV0PFEINFP6000	Mary Criddle	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_DAY2_POSTVAX1_S

Form: CENTRAL LAB SAMPLE COLLECTION - eCRF Audit Trail History

Form Version: 12-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

10:28:16 (UTC-05:00) Eastern Time (US & Canada)		(pfe.mcriddle)	CLINICAL CHEMISTRY	
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3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-19-2020 10:28:16 (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
Jun-19-2020 10:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: YES	Initial Entry

3.b

Date	Location	User	Value	Reason
Jun-19-2020 10:28:16 (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

090177e196ae3d67\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: 12-Jun-2020 21:47

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

3.b Lab Panel:

Date	Location	User	Value	Reason
Jun-19-2020 10:28:16 (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
Jun-19-2020 10:28:16 (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
Jun-19-2020 10:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: YES	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jun-24-2020 13:36:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/24/2020	Initial Entry

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 19-Jun-2020 21:49

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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

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1. Exam Date:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examine d: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
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090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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

Jun-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result:	Initial Entry
			SKIN	
			NORMAL	

2.b Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result:	Initial Entry
			HEAD	
			NORMAL	

090177e196ae3d67\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: 10031038

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.c Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: EYES Result: NOT DONE	Initial Entry

2.d Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\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: 10031038

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.e

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

090177e196ae3d67\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: 10031038

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 13:54:56 (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-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: THROAT Result: NOT DONE	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\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: 10031038

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

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

2.h Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

090177e196ae3d67\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: 10031038

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.i Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: ABDO MEN Result: NOT DONE	Initial Entry

2.j Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\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: 10031038

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.k

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: MUSCULO SKELETAL Result: NOT DONE	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: EXTREM ITIES Result: NORMAL	Initial Entry

090177e196ae3d67\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: 10031038

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.l Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: EXTREMITIES	Initial Entry

2.l Result:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: NEUROL OGICAL Result: NOT DON E	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System LYMPH N Examined: ODES Result: NORMAL	Initial Entry

2.n Body System Examined:

Date	Location	User	Value	Reason
Jun-24-2020 13:54:56 (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-24-2020 13:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V3_WEEK1_POSTVAX1_S

Form Version: 19-Jun-2020 21:48

Site No: 1003

Subject No: 10031038

Generated By: pfe.lewissc

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

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1. Date:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/24/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jun-24-2020 13:55:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Record Identifier: Temperature: 97.2 Temperature Unit: Temperature Location: FOREH Systolic: 133 Diastolic: 76 BP Position: SITTING Pulse: 68	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:28 (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
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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Jun-24-2020 13:55:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 97.2	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:28 (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-24-2020 13:55:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 133	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 76	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:28 (UTC-05:00) Eastern	ACV0PFEINFP6000	Emily Pierce	Data Entry: SITTING	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

Time (US & Canada)		(pfe.epierce)	
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2.a Pulse:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 68	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Collection Date:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jun/24/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jun-24-2020 13:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Category for CLINICAL Lab Test: CHEMISTR Y Subcategory BLOOD CH for Lab Test EMISTRY : Lab Sub-Pa YES nel Collecte d:	Initial Entry

3.a Lab Panel:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:42 (UTC-05:00) Eastern	ACV0PFEINFP6000	Emily Pierce	Data Entry: CLINICAL CHEMISTRY	Initial Entry

090177e196ae3d67\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: 10031038 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

Time (US & Canada)		(pfe.epierce)	
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3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:42 (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-24-2020 13:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES	Initial Entry

3.b

Date	Location	User	Value	Reason
Jun-24-2020 13:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Category for L HEMATO ab Test: LOGY Subcategory fo DIFFERE r Lab Test: NTIAL Lab Sub-Panel YES Collected:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

3.b Lab Panel:

Date	Location	User	Value	Reason
Jun-24-2020 13:55:42 (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-24-2020 13:55:42 (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-24-2020 13:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Jun-24-2020 13:55:53 (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 13:55:53 (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 15:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-24-2020 13:55:53 (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 13:55:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES Date of Collection: Jun/24/2020	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

5.a

Date	Location	User	Value	Reason
Jun-24-2020 15:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8F8D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 15:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8F8D	Initial Entry

5.b

Date	Location	User	Value	Reason
Jun-24-2020 15:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8F8F	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 15:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8F8F	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

Jun-24-2020 15:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8F8G	Initial Entry
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5.c Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 15:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8F8G	Initial Entry

5.d

Date	Location	User	Value	Reason
Jun-24-2020 15:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8F8H	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 15:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8F8H	Initial Entry

5.e

Date	Location	User	Value	Reason
Jun-24-2020 15:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8F8J	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

5.e Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 15:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8F8J	Initial Entry

5.f

Date	Location	User	Value	Reason
Jun-24-2020 15:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFLN	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 15:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFLN	Initial Entry

5.g

Date	Location	User	Value	Reason
Jun-24-2020 15:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFLP	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

5.g Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 15:49:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFLP	Initial Entry

5.h

Date	Location	User	Value	Reason
Jun-24-2020 15:49:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFLR	Initial Entry

5.h Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 15:49:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFLR	Initial Entry

5.i

Date	Location	User	Value	Reason
Jun-24-2020 15:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFLS	Initial Entry

090177e196ae3d67\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: 10031038

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.i Sample ID

Date	Location	User	Value	Reason
Jun-24-2020 15:49:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFLS	Initial Entry

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jul-08-2020 09:22:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jul/8/2020	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Symptom:: FE V E R Were fever or systemi N c symptoms present o O n the last day the Subj ect Diary was complet ed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	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-08-2020 09:22:57 (UTC-05:00) Eastern	ACV0PFEINFP6000	Emily Pierce	Data Entry: NO	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)		(pfe.epierce)	
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2.b

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Symptom:: FA TI GU E Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?: NO	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 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-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Symptom:: HE AD	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

			AC HE Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	
--	--	--	---	--

2.c Symptom:

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<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-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	<u>Data Entry:</u> Symptom:: C HI LL S Were fever or systemi N c symptoms present o O n the last day the Sub ject Diary was comple ted?:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.d Symptom:

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Symptom:: VO MI TIN G Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.e Symptom:

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 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-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Symptom:: DI AR RH EA Were fever or system NO ic symptoms present on the last day the S ubject Diary was co mpleted?:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.f Symptom:

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 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-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Symptom:: NEW O R WOR SENE MUSCL E PAIN Were fever or sy NO stemic symptom s present on the l ast day the Subj ect Diary was co mpleted?:	Initial Entry

090177e196ae3d67\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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.g Symptom:

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NEW OR WORSENER M USCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Symptom:: NEW O R WOR SENER JOINT PAIN Were fever or sys NO temic symptoms present on the la st day the Subjec t Diary was com pleted?:	Initial Entry

090177e196ae3d67\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: 10031038 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

2.h Symptom:

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NEW OR WORSENE JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (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-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Injection Site Reaction: REDNESS SWELLING	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Injection Site Reaction: SWELLING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d67\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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	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-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	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

090177e196ae3d67\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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

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-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	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-08-2020 09:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NO	Initial Entry

090177e196ae3d67\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: 10031038

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

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1. Exam Date:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jul/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examine d: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
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090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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

Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result:	Initial Entry
			SKIN	
			NORMAL	

2.b Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result:	Initial Entry
			HEAD	
			NORMAL	

090177e196ae3d67\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: 10031038

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.c Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: EYES Result: NORMAL	Initial Entry

2.d Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

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Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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Site No: 1003

Subject No: 10031038

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.e

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NORMAL	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

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Site No: 1003

Subject No: 10031038

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-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: THROAT Result: NORMAL	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

090177e196ae3d67\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: 10031038

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

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NORMAL	Initial Entry

2.h Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NORMAL	Initial Entry

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Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

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Site No: 1003

Subject No: 10031038

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.i Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: ABDO MEN Result: NOT D ONE	Initial Entry

2.j Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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.k

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: MUSCULO SKELETAL Result: NOT DONE	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: EXTREMITY NORMA L	Initial Entry

090177e196ae3d67\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: 10031038

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: NEUROL OGICAL Result: NOT DON E	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System LYMPH N Examined: ODES Result: NORMAL	Initial Entry

2.n Body System Examined:

Date	Location	User	Value	Reason
Jul-08-2020 09:24:57 (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
Jul-08-2020 09:24:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

090177e196ae3d67\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: 10031038

Generated By: pfe.lewissc

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

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1. Date:

Date	Location	User	Value	Reason
Jul-08-2020 09:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jul/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-08-2020 09:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Record Identifier:: Temperature: 97.6 Temperature Unit: Temperature Location: FOREH Systolic:: 149 Diastolic:: 82 BP Position: SITTING Pulse:: 68	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jul-08-2020 09:26:15 (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
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090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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

Jul-08-2020 09:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 97.6	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Jul-08-2020 09:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jul-08-2020 09:26:15 (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
Jul-09-2020 01:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 1: Closed	Response satisfies query
Jul-08-2020 09:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Query 1: Answered	Original value is correct
Jul-08-2020 09:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 149 is outside of Normal Range 90 - 140.
Jul-08-2020 09:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 149	Initial Entry

2.a Diastolic:

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Header Text: c4591001

Visit: V4_WEEK3_VAX2_S

Form Version: 06-Jul-2020 21:54

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jul-08-2020 09:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 82	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jul-08-2020 09:26:15 (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
Jul-08-2020 09:26:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 68	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Jul-08-2020 09:26:26 (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-08-2020 09:26:26 (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-08-2020 12:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-08-2020 09:26:26 (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-08-2020 09:26:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES Date of Collection: Jul/8/2020	Initial Entry

090177e196ae3d67\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: 10031038 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

5.a

Date	Location	User	Value	Reason
Jul-08-2020 12:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8D64	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-08-2020 12:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8D64	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Jul-08-2020 09:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jul-08-2020 09:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jul/8/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-08-2020 09:26:37 (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-08-2020 09:26:37 (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-08-2020 09:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SY NDROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jul-08-2020 09:26:37 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTI	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)			C TEST	
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6. Trade Name:

Date	Location	User	Value	Reason
Jul-08-2020 09:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CEPHEID XPRT XPRESS SARS-COV-2 TEST	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jul-08-2020 09:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Collection Date:

Date	Location	User	Value	Reason
Jul-08-2020 09:27:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jul/8/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-08-2020 09:27:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jul-08-2020 09:27:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Category for CLINICAL Lab Test: CHEMISTR Y Subcategory BLOOD CH for Lab Test EMISTRY : Lab Sub-Pa YES nel Collecte d:	Initial Entry

3.a Lab Panel:

Date	Location	User	Value	Reason
Jul-08-2020 09:27:01 (UTC-05:00) Eastern	ACV0PFEINFP6000	Emily Pierce	Data Entry: CLINICAL CHEMISTRY	Initial Entry

090177e196ae3d67\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: 10031038 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

Time (US & Canada)		(pfe.epierce)	
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3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-08-2020 09:27:01 (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
Jul-08-2020 09:27:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES	Initial Entry

3.b

Date	Location	User	Value	Reason
Jul-08-2020 09:27:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Category for L HEMATO ab Test: LOGY Subcategory fo DIFFERE r Lab Test: NTIAL Lab Sub-Panel YES Collected:	Initial Entry

090177e196ae3d67\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: 10031038 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

3.b Lab Panel:

Date	Location	User	Value	Reason
Jul-08-2020 09:27:01 (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
Jul-08-2020 09:27:01 (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
Jul-08-2020 09:27:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Jul-08-2020 09:27:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-08-2020 09:27:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-08-2020 12:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-08-2020 09:27:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-08-2020 09:27:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES Date of Collection: Jul/8/2020	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

5.a

Date	Location	User	Value	Reason
Jul-08-2020 12:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8D59	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-08-2020 12:06:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8D59	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-08-2020 12:06:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8D5B	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-08-2020 12:06:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8D5B	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-08-2020 12:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8D5C	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

5.c Sample ID

Date	Location	User	Value	Reason
Jul-08-2020 12:06:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8D5C	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-08-2020 12:06:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8D5D	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jul-08-2020 12:06:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8D5D	Initial Entry

5.e

Date	Location	User	Value	Reason
Jul-08-2020 12:06:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8D5F	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jul-08-2020 12:06:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8D5F	Initial Entry

5.f

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jul-08-2020 12:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFVC	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Jul-08-2020 12:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFVC	Initial Entry

5.g

Date	Location	User	Value	Reason
Jul-08-2020 12:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFVD	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jul-08-2020 12:07:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFVD	Initial Entry

5.h

Date	Location	User	Value	Reason
Jul-08-2020 12:07:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFVF	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

5.h Sample ID

Date	Location	User	Value	Reason
Jul-08-2020 12:07:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFVF	Initial Entry

5.i

Date	Location	User	Value	Reason
Jul-08-2020 12:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFVG	Initial Entry

5.i Sample ID

Date	Location	User	Value	Reason
Jul-08-2020 12:07:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFVG	Initial Entry

090177e196ae3d67\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: 10031038

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jul-08-2020 10:37:14 (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-08-2020 10:37:14 (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-08-2020 10:37:14 (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-08-2020 10:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: Jul/8/2020 09:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jul-08-2020 10:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae3d67\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: 10031038

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

6. Body Side:

Date	Location	User	Value	Reason
Jul-08-2020 10:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jul-08-2020 10:37:14 (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-08-2020 10:37:14 (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-08-2020 10:37:14 (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-08-2020 10:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIE D OBSERVATION PERIOD	Initial Entry

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

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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
Jul-08-2020 10:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jul-14-2020 09:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jul/14/2020	Initial Entry

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031038

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

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1. Exam Date:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jul/14/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examine d: GENERAL APPEARANCE Result: NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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

Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result:	Initial Entry
			SKIN	
			NORMAL	

2.b Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result:	Initial Entry
			HEAD	
			NORMAL	

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031038

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.c Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: EYES Result: NORMAL	Initial Entry

2.d Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

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Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031038

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.e

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031038

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-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: THROAT Result: NOT DONE	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031038

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

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

2.h Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: Result: NORMAL	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031038

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.i Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: ABDO MEN Result: NOT D ONE	Initial Entry

2.j Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.k

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: MUSCULO SKELETAL Result: NOT DONE	Initial Entry

2.k Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: EXTREMITY NORMA L	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031038

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

2.1 Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System Examined: NEUROL OGICAL Result: NOT DON E	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:55

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Body System LYMPH N Examined: ODES Result: NORMAL	Initial Entry

2.n Body System Examined:

Date	Location	User	Value	Reason
Jul-14-2020 09:48:37 (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
Jul-14-2020 09:48:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: NORMAL	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_S

Form Version: 06-Jul-2020 21:54

Site No: 1003

Subject No: 10031038

Generated By: pfe.lewissc

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

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1. Date:

Date	Location	User	Value	Reason
Jul-14-2020 09:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jul/14/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-14-2020 09:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Record Identifier: Temperature: 98.0 Temperature Unit: F Temperature Location: FOREHEAD Systolic: 142 Diastolic: 86 BP Position: SITTING Pulse: 59	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jul-14-2020 09:49:26 (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
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090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

Jul-14-2020 09:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 98.0	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Jul-14-2020 09:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Jul-14-2020 09:49:26 (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
Jul-15-2020 01:19:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe.newtod07)	Query 1: Closed	Response satisfies query
Jul-14-2020 09:53:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	Original value is correct
Jul-14-2020 09:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 142 is outside of Normal Range 90 - 140.
Jul-14-2020 09:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 142	Initial Entry

2.a Diastolic:

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jul-14-2020 09:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 86	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jul-14-2020 09:49:26 (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
Jul-14-2020 09:49:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: 59	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Collection Date:

Date	Location	User	Value	Reason
Jul-14-2020 09:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Jul/14/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-14-2020 09:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

3.a

Date	Location	User	Value	Reason
Jul-14-2020 09:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Category for CLINICAL Lab Test: CHEMISTR Y Subcategory BLOOD CH for Lab Test EMISTRY : Lab Sub-Pa YES nel Collecte d:	Initial Entry

3.a Lab Panel:

Date	Location	User	Value	Reason
Jul-14-2020 09:49:37 (UTC-05:00) Eastern	ACV0PFEINFP6000	Emily Pierce	Data Entry: CLINICAL CHEMISTRY	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001
Visit: V5_WEEK1_POSTVAX2_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: 10031038 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

Time (US & Canada)		(pfe.epierce)	
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3.a Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-14-2020 09:49:37 (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
Jul-14-2020 09:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES	Initial Entry

3.b

Date	Location	User	Value	Reason
Jul-14-2020 09:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: Category for L HEMATO ab Test: LOGY Subcategory fo DIFFERE r Lab Test: NTIAL Lab Sub-Panel YES Collected:	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V5_WEEK1_POSTVAX2_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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

3.b Lab Panel:

Date	Location	User	Value	Reason
Jul-14-2020 09:49:37 (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
Jul-14-2020 09:49:37 (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
Jul-14-2020 09:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Jul-14-2020 09:49:50 (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-14-2020 09:49:50 (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-14-2020 12:05:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-14-2020 09:49:50 (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-14-2020 09:49:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Emily Pierce (pfe.epierce)	Data Entry: YES Date of Collection: Jul/14/2020	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

5.a

Date	Location	User	Value	Reason
Jul-14-2020 12:05:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8DBH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-14-2020 12:05:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8DBH	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-14-2020 12:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8DBJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-14-2020 12:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8DBJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-14-2020 12:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8DBK	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Jul-14-2020 12:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8DBK	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-14-2020 12:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8DBL	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jul-14-2020 12:06:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8DBL	Initial Entry

5.e

Date	Location	User	Value	Reason
Jul-14-2020 12:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BN8DBM	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jul-14-2020 12:06:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BN8DBM	Initial Entry

5.f

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jul-14-2020 12:14:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFZ3	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Jul-14-2020 12:14:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFZ3	Initial Entry

5.g

Date	Location	User	Value	Reason
Jul-14-2020 12:14:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFZ4	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jul-14-2020 12:14:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFZ4	Initial Entry

5.h

Date	Location	User	Value	Reason
Jul-14-2020 12:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFZ5	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

5.h Sample ID

Date	Location	User	Value	Reason
Jul-14-2020 12:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFZ5	Initial Entry

5.i

Date	Location	User	Value	Reason
Jul-14-2020 12:14:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFZ6	Initial Entry

5.i Sample ID

Date	Location	User	Value	Reason
Jul-14-2020 12:14:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFZ6	Initial Entry

090177e196ae3d67\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: 10031038

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jul-20-2020 13:44:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jul/20/2020	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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: FE V ER Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	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-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.b

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: FA TI GU E Were fever or systemic NO symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.b Symptom:

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 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-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

			Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:	
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2.c Symptom:

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<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-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Symptom:: C HI LL S Were fever or systemic N symptoms present on t O he last day the Subject Diary was completed?:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.d Symptom:

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: VO MI TIN G Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.e Symptom:

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 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-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: DI AR RH EA Were fever or systemi NO c symptoms present o n the last day the Subj ect Diary was complet ed?:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.f Symptom:

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 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-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: NEW O R WOR SENE MUSCL E PAIN Were fever or sys NO temic symptoms present on the las t day the Subject Diary was comple ted?:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

2.g Symptom:

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NEW OR WORSENERED MU SCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Symptom:: NEW O R WOR SENERED JOINT P AIN Were fever or syst NO emic symptoms p resent on the last day the Subject D iary was complete d?:	Initial Entry

090177e196ae3d67\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:** 10031038**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04**2.h Symptom:**

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NEW OR WORSENER JOI NT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (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-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Injection Site Reactio RE n:: DN ES S	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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Injection Site Reaction: SWELLING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	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-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	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

090177e196ae3d67\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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Jul-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	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-20-2020 13:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NO	Initial Entry

090177e196ae3d67\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: 10031038

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

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1. Exam Date:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jul/20/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examine d: Result: GENERAL APPEARANCE NORMAL	Initial Entry

2.a Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (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-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.b

Date	Location	User	Value	Reason
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090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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

Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: SKIN Result: NORM AL	Initial Entry
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2.b Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (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
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: HEAD Result: NORM AL	Initial Entry

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Header Text: c4591001

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Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.c Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (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-20-2020 13:45:20 (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-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Body System Examined: EYES Result: NORMAL	Initial Entry

2.d Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EYES	Initial Entry

2.d Result:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NORMAL	Initial Entry

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Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031038

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: ---

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2.e

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: Result: EARS NOT DONE	Initial Entry

2.e Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (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-20-2020 13:45:20 (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-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: Result: NOSE NOT DONE	Initial Entry

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Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

Form: PHYSICAL EXAMINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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2.f Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (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-20-2020 13:45:20 (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-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Body System Examined: THROAT <u>Result:</u> NOT DONE	Initial Entry

2.g Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (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-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NOT DONE	Initial Entry

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Header Text: c4591001

Visit: V6_WEEK2_POSTVAX2_S

Form Version: 17-Jul-2020 21:54

Site No: 1003

Subject No: 10031038

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

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

2.h Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (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-20-2020 13:45:20 (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-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: Result: NOT DONE	Initial Entry

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Header Text: c4591001

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Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.i Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> LUNGS	Initial Entry

2.i Result:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NOT DONE	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Body System Examined: ABDOMEN <u>Result:</u> NOT DONE	Initial Entry

2.j Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> ABDOMEN	Initial Entry

2.j Result:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NOT DONE	Initial Entry

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Generated By: pfe.levisse

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Subject Initials: ---

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2.k

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (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-20-2020 13:45:20 (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-20-2020 13:45:20 (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-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: EXTREMITIES Result: NORMAL	Initial Entry

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Header Text: c4591001

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Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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.l Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> EXTREMITIES	Initial Entry

2.l Result:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NORMAL	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> Body System Examined: NEUROLOGICAL Result: NOT DONE	Initial Entry

2.m Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NEUROLOGICAL	Initial Entry

2.m Result:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	<u>Data Entry:</u> NOT DONE	Initial Entry

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Header Text: c4591001

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Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Body System Examined: LYMPH N ODES Result: NORMAL	Initial Entry

2.n Body System Examined:

Date	Location	User	Value	Reason
Jul-20-2020 13:45:20 (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-20-2020 13:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: NORMAL	Initial Entry

090177e196ae3d67\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: 10031038

Generated By: pfe.lewissc

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

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1. Date:

Date	Location	User	Value	Reason
Jul-20-2020 13:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Jul/20/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-20-2020 13:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Record Identifier: 1 Temperature: 98.1 Temperature Unit: Temperature Location: FOREHEAD Systolic: 153 Diastolic: 87 BP Position: SITTING Pulse: 58	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jul-20-2020 13:47:38 (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
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090177e196ae3d67\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: 10031038

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

Jul-20-2020 13:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 98.1	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Jul-20-2020 13:47:38 (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
Jul-20-2020 13:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: FOREHEAD	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jul-22-2020 00:17:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sanjay Mishra (pfe.mishrs01)	Query 1: Closed	Response satisfies query
Jul-21-2020 07:14:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	NCS
Jul-21-2020 01:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sanjay Mishra (pfe.mishrs01)	Query 1: Reissued:Open ed	Re-query1: Thanks for response "Original value is correct". However, please confirm the value is CS or NCS. Thank you.

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Jul-20-2020 13:47:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Query 1: Answered	Original value is correct
Jul-20-2020 13:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 153 is outside of Normal Range 90 - 140.
Jul-20-2020 13:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 153	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jul-20-2020 13:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 87	Initial Entry

2.a BP Position:

Date	Location	User	Value	Reason
Jul-20-2020 13:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: SITTING	Initial Entry

2.a Pulse:

Date	Location	User	Value	Reason
Jul-20-2020 13:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: 58	Initial Entry

090177e196ae3d67\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: 10031038

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-20-2020 13:47:45 (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-20-2020 13:47:45 (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-20-2020 14:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jul-20-2020 13:47:45 (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-20-2020 13:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Collection: Jul/20/2020	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

5.a

Date	Location	User	Value	Reason
Jul-20-2020 14:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BGJG3T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jul-20-2020 14:45:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BGJG3T	Initial Entry

5.b

Date	Location	User	Value	Reason
Jul-20-2020 14:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BGJG3V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jul-20-2020 14:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BGJG3V	Initial Entry

5.c

Date	Location	User	Value	Reason
Jul-20-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BGJG3W	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

5.c Sample ID

Date	Location	User	Value	Reason
Jul-20-2020 14:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BGJG3W	Initial Entry

5.d

Date	Location	User	Value	Reason
Jul-20-2020 14:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BGJG3X	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Jul-20-2020 14:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BGJG3X	Initial Entry

5.e

Date	Location	User	Value	Reason
Jul-20-2020 14:45:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BGJG3Y	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Jul-20-2020 14:45:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BGJG3Y	Initial Entry

5.f

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Jul-20-2020 14:45:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFD7	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Jul-20-2020 14:45:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFD7	Initial Entry

5.g

Date	Location	User	Value	Reason
Jul-20-2020 14:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFD8	Initial Entry

5.g Sample ID

Date	Location	User	Value	Reason
Jul-20-2020 14:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFD8	Initial Entry

5.h

Date	Location	User	Value	Reason
Jul-20-2020 14:46:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFDC	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

5.h Sample ID

Date	Location	User	Value	Reason
Jul-20-2020 14:46:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFDC	Initial Entry

5.i

Date	Location	User	Value	Reason
Jul-20-2020 14:46:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNYFDD	Initial Entry

5.i Sample ID

Date	Location	User	Value	Reason
Jul-20-2020 14:46:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNYFDD	Initial Entry

090177e196ae3d67\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: 10031038

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

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-11-2020 07:59:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Aug/11/2020	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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Aug-11-2020 08:01:55 (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-11-2020 08:01:55 (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-11-2020 14:20:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-11-2020 08:01:55 (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-11-2020 08:01:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3d67\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: 10031038

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

			Aug/11/2020	
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5.a

Date	Location	User	Value	Reason
Aug-11-2020 14:20:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BP578L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 14:20:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BP578L	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-11-2020 14:20:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BP578M	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 14:20:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BP578M	Initial Entry

5.c

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-11-2020 14:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BP578N	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 14:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BP578N	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-11-2020 14:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BP578P	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 14:20:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BP578P	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-11-2020 14:20:32 (UTC-05:00) Eastern	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BP578R	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissu

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

Time (US & Canada)				
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 14:20:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BP578R	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-11-2020 14:27:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BKDZ3F	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 14:27:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BKDZ3F	Initial Entry

5.g

Date	Location	User	Value	Reason
Aug-11-2020 14:27:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BKDZ3G	Initial Entry

090177e196ae3d67\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: 10031038

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-11-2020 14:27:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BKDZ3G	Initial Entry

5.h

Date	Location	User	Value	Reason
Aug-11-2020 14:27:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BKDZ3H	Initial Entry

5.h Sample ID

Date	Location	User	Value	Reason
Aug-11-2020 14:27:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BKDZ3H	Initial Entry

090177e196ae3d67\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: 10031038

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-30-2020 07:53:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschnegebunger)	Data Entry: Dec/30/2020	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: 10031038

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
Dec-30-2020 07:53:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-30-2020 07:53:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-30-2020 10:30:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-30-2020 07:53:58 (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.
Dec-30-2020 07:53:58 (UTC-05:00)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

Eastern Time (US & Canada)

Dec/30/2020

5.a

Date	Location	User	Value	Reason
Dec-30-2020 10:30:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BPYLF9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 10:30:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BPYLF9	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-30-2020 10:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNWKPP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 10:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNWKPP	Initial Entry

5.c

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Dec-30-2020 10:30:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BNWKPR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 10:30:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BNWKPR	Initial Entry

090177e196ae3d67\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: 10031038

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 10:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: Feb/25/2021	Initial Entry

Header Text: c4591001

Visit: V8A_VAX3

Form: INFORMED CONSENT - BOOSTER - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:11

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Consent Was:

Date	Location	User	Value	Reason
Feb-25-2021 10:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: OBTAINED Date Written Consent Obtained Feb/25/2021	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-25-2021 10:33:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: Feb/25/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-25-2021 10:33:36 (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
Feb-25-2021 10:33:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d67\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: 10031038

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Feb-25-2021 10:34:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: Feb/25/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-25-2021 10:34:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: Record Identifier:: Temperature: 96.1 Temperature Unit: Temperature Location:: ORAL C AVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-25-2021 10:34:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Feb-26-2021 03:04:13 (UTC-05:00) Eastern	ACV0PFEINFP6000	Natasha Rajkumar (pfe.rajkun)	Query 1: Closed	Response satisfies query

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: V8A_VAX3

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:16

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)				
Feb-25-2021 10:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	Original value is correct
Feb-25-2021 10:34:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.1 F is outside of Normal Range 97 - 99.5 F.
Feb-25-2021 10:34:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: 96.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Feb-25-2021 10:34:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Feb-25-2021 10:34:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-25-2021 10:34:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-25-2021 10:34:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-25-2021 11:30:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 10:34:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 10:34:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

			Feb/25/2021	
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5.a

Date	Location	User	Value	Reason
Feb-25-2021 11:30:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BPYLS3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 11:30:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BPYLS3	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-25-2021 11:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BVR34V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 11:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BVR34V	Initial Entry

5.c

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Feb-25-2021 11:37:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BVR34W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 11:37:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BVR34W	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-25-2021 10:34:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-25-2021 10:34:35 (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
Feb-25-2021 11:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-25-2021 10:34:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-25-2021 10:34:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3d67\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: 10031038 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

			Feb/25/2021	
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5.a

Date	Location	User	Value	Reason
Feb-25-2021 11:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BPYLRX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-25-2021 11:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BPYLRX	Initial Entry

090177e196ae3d67\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: 10031038

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-25-2021 10:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-25-2021 10:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-25-2021 10:35:01 (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
Feb-25-2021 10:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: Feb/25/2021 09:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-25-2021 10:35:01	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3d67\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: 10031038

Generated By: pfe.levisse

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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	DELTOID MUSCLE	
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6. Body Side:

Date	Location	User	Value	Reason
Feb-25-2021 10:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-25-2021 10:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-25-2021 10:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-25-2021 10:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-25-2021 10:35:01 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)

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

Date	Location	User	Value	Reason
Feb-25-2021 10:35:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	<u>Data Entry:</u> YES	Initial Entry

Header Text: c4591001

Visit: V8B_WEEK1_POSTVAX3

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-04-2021 08:33:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcridle)	Data Entry: Mar/4/2021	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-04-2021 08:34:11 (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-04-2021 08:34:11 (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-04-2021 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-04-2021 08:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-04-2021 08:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Data Entry: YES Date of Collection:	Initial Entry

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

Mar/4/2021

5.a

Date	Location	User	Value	Reason
Mar-04-2021 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BPYLV6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 14:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BPYLV6	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-04-2021 14:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BVR37Z	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 14:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BVR37Z	Initial Entry

5.c

090177e196ae3d67\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: 10031038

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Mar-04-2021 14:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: Sample ID: BVR380	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 14:48:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Madison Murphy (pfe.mmurphy)	Data Entry: BVR380	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - 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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Aug-11-2020 08:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: Aug/11/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-11-2020 08:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-11-2020 08:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Megan Helf (pfe.ahelf)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d67\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: 10031038

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

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Date	Location	User	Value	Reason
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Dec-31-2020 12:31:24 (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
Dec-31-2020 12:31:24 (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
Jan-21-2021 00:51:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Query closed; will follow for SAE update with the requested clinical course info
Jan-20-2021 10:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 2: Answered	only after visit summary is available. appendectomy was laparoscopic
Jan-18-2021 08:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical Followup - Please request medical records for information on

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

090177e196ae3d67\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: 10031038

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

				appendectomy date & type (laparoscopic or not), presenting symptoms, surgical / pathologic findings; treatment regimen & other info)
Jan-14-2021 15:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Query closed; will follow for SAE update with the requested appendicitis event info
Jan-14-2021 14:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	hospital records will be obtained on 18 Jan 2021.
Jan-06-2021 10:37:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Please request medical records for information on appendectomy date & type (laparoscopic or not), presenting symptoms, surgical / pathologic findings; treatment regimen & other info)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: appendicitis	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: Sep/19/2020 UNK:U NK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: NO End Date Time: Sep/23/2020 UNK: UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1003

Subject No: 10031038

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-16-2021 17:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Response satisfies query
Jan-29-2021 08:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 4: Answered	the phrase abdominal pain that was intolerable has been updated in a safety report and faxed today
Jan-27-2021 12:45:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	Clinical SAE report states 'Prior to hospitalization, subject experienced abdominal that was intolerable.'; please clarify if missing word after Abd is 'pain'; please update SAE with missing word
Jan-25-2021 22:02:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Jan-22-2021 09:48:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 3: Answered	safety form updated and sent on 21 Jan 2021
Jan-18-2021 08:50:02 (UTC-05:00)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE.

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090177e196ae3d67\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: 10031038 Generated By: pfe.levisse					Form: ADVERSE EVENT REPORT - eCRF Audit Trail History Form Status: Data Complete, Frozen Site Name: (1003) Rochester Regional HealthRochester General Hospital Subject Initials: --- Generated Time (GMT): 29-Mar-2021 04:04				
Eastern Time (US & Canada)					Please submit a follow-up SAE form [#2021001152] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.				
Jan-14-2021 15:53:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed		Clinical Thank you; please submit the 19Sep20 COVID test result to the SAE laboratory section				
Jan-14-2021 14:49:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 2: Answered		subject had a COVID test on 19 Sep 2020 prior to appendectomy. results negative. hospital records will be obtained for SAE details for Pfizer Safety on 18 Jan 2021				
Jan-06-2021 10:35:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened		Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021001152] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.				
Jan-02-2021 06:05:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Deleted		SAE RECON:appendicitis(Onset date:19Sep2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is				

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1003

Subject No: 10031038

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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

				not serious, downgrade the event on AE CRF
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE appendicitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	<p>Data Entry: YES</p> <p>Is this serious event as associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant di</p>	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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Site No: 1003

Subject No: 10031038

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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			sability/inc apacity? NO Is this serio us event lif e threatenin g? NO Other medi cally impor tant serious event NO	
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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
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: NOT RELATED If Not Related to stu dy treatment(s), this event is due to: OTHER	Initial Entry

Header Text: c4591001

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Subject No: 10031038

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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			<i>If Other, specify:</i>	
			appendicitis	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-21-2021 00:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-20-2021 10:51:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Mary Criddle (pfe.mcriddle)	Query 1: Answered	Data is not in subject record
Jan-06-2021 10:26:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - AE report states a Con Med given; however, SAE does not include any medication information (including antibiotics)

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Header Text: c4591001

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Generated By: pfe.lewissc

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Form Status: Data Complete, Frozen

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject Initials: ---

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				yes/no). Please review, harmonize reporting, and update in the appropriate location.
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 12:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-31-2020 12:31:24 (UTC-05:00)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: NO	Initial Entry

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Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen
Site No: 1003 **Site Name:** (1003) Rochester Regional HealthRochester General Hospital
Subject No: 10031038 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

Eastern Time (US & Canada)				
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-04-2021 04:25:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021001152	Initial Entry

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 10:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: Feb/11/2021	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Feb-25-2021 10:32:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Marie Francis (pfe.mfrancis)	Data Entry: The participant will return for consent/eligibility asses sment for the booster dose 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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-30-2020 07:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: Dec/30/2020	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

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: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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

Date	Location	User	Value	Reason
Dec-30-2020 07:54:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneeggenburger)	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

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-30-2020 07:54:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: Dec/30/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-30-2020 07:54:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Lauren Mitchell (pfe.lschneggenburger)	Data Entry: ASSESS ELIGIBILIT Y FOR ADDITIONA L VACCINATION	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Subject Status

Date	Location	User	Value	Reason
Aug-11-2020 08:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jun-17-2020 10:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZE D	Initial Entry
Jun-10-2020 07:58:38 (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
Aug-11-2020 08:02:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/11/2020	Initial Entry
Jun-17-2020 10:40:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jun/17/2020	Initial Entry
Jun-10-2020 07:58:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jun/5/2020	Initial Entry

090177e196ae3d67\Final\Final On: 01-Apr-2021 04:33 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1003

Site Name: (1003) Rochester Regional HealthRochester General Hospital

Subject No: 10031038

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Aug-24-2020 20:56:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Edward Walsh (pfe.ewalsh)	Data Entry: Click Here to Enable	Initial Entry