

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[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	30 JUN 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jul/31/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11401009]
2.	Birth Date:	(b) (6)/1979
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:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jul/31/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[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
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

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Form Version: 30-Jul-2020 21:27

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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
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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

2.e	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.f	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.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01
2.k	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.l	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 m	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: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Jul/31/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	Nov/1/1985
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gout]
	Start Date:	Sep/1/2013
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to cats]
	Start Date:	Aug/1/1988
	Ongoing:	YES
1.d	Line/MH Number:	[]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[]
	Start Date:	Jun/1/1997
	Ongoing:	NO End Date: Jun/1/1997

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to bees]
	Start Date:	Aug/1/1988
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to shrimp]
	Start Date:	Aug/1/1988
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[allergy to penicillin]
	Start Date:	Aug/1/1988
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/31/2020
2.	Weight:	[224.6]
3.	Unit:	LB
4.	Height:	[72.36]
5.	Unit:	in
6.	Body Mass Index:	[30.2]

Vital Signs Details

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Jul/31/2020
2.	Randomization Number:	[40104]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/31/2020
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	[BPG57C]
5.b	Sample ID	[BPG57D]
5.c	Sample ID	[BNB416]
5.d	Sample ID	[BNB417]
5.e	Sample ID	[BNB418]

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jul/31/2020
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	[BNB419]
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[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/31/2020 09:28
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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
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

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/20/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/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	[BPYZLR]
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/20/2020 14:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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
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

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/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	[BPYZ56]
5.b	Sample ID	[BNWXLW]
5.c	Sample ID	[BNWXLX]
5.d	Sample ID	[BNWXLY]

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/11/2021
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	[BRFJD8]
5.b	Sample ID	[BSGRDP]
5.c	Sample ID	[BSGRDR]

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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/21/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Aug/21/2020
2.	Date of First Symptom Started:	Aug/21/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Aug/24/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.	Symptoms - Other Text:	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Aug/21/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Aug/21/2020	Comments
2.	Specimen Type:	SWABBED MATERIAL	Comments
3.	Specimen Collection Location:	NASOPHARYNX	Comments
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Comments
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	Comments
6.	Trade Name:	OTHER	Comments
7.	Test Result:	NEGATIVE	Comments
8.	Comments/Findings/Details:	[]	Comments
9.	Trade Name Other, Specify:	[Rheonix COVID-19 MDx assay]	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Aug/21/2020
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	[RW86831]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: HEALTH CARE UTILIZATION

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: HEALTH CARE UTILIZATION

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Respiratory Treatment

1.	What is the treatment Identifier?	Not Applicable _____ []	Comments
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
3.	Treatment:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
 Visit on Aug/21/2020
Form Version: 30-Jul-2020 21:27 **Form Status:** Data Complete, Frozen, Verified
Site No: 1140 **Site Name:** (1140) SUNY Upstate Medical University
Subject No: 11401009 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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Lab Chemistry Details

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5 f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Laboratory Data Hematology

1.	Lab Panel:	Not Applicable _____	Comments
2.	Laboratory Name and Address	Not Applicable _____ []	Comments
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Specimen Type:	Not Applicable _____	Comments

Lab Result

5.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.d	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5 f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5 h	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.i	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.j	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled

Form: VITAL SIGNS - COVID

Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ []	Comments
	Diastolic:	Not Applicable _____ []	Comments
	Respiratory Rate in respirations/minute:	Not Applicable _____ []	Comments
	Heart Rate in beats/minute:	Not Applicable _____ []	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Date Time of Assessment	Arterial Blood Gases PaO ₂	FiO ₂ (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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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.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled

Form: IMAGING

Visit on Aug/21/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Imaging

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Location of Assessment:	Not Applicable _____	Comments
3.	Type of Imaging Exam:	Not Applicable _____	Comments
4.	Assessment:	Not Applicable _____	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Oct/13/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Visit on Oct/13/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYZCD]
5.b	Sample ID	[BPG5X4]
5.c	Sample ID	[BPG5XL]

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (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: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Sep/17/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Injection Site Swelling	Jul/31/2020 12:00	NO End Date Time: Aug/1/2020 08:00	Repeating Pages
2.	ADVERSE EVENT	2	Injection Site Pain	Jul/31/2020 12:00	NO End Date Time: Aug/1/2020 08:00	Repeating Pages
3. DELETED	ADVERSE EVENT	3	Fever	Aug/21/2020 07:00	YES	Repeating Pages
4. DELETED	ADVERSE EVENT	4	Bee Sting	Aug/28/2020 14:00	NO End Date Time: Aug/28/2020 14:00	Repeating Pages
5.	ADVERSE EVENT	5	Anaphylaxis Status Post Bee Sting	Aug/28/2020 14:00	NO End Date Time: Aug/28/2020 20:00	Repeating Pages
6.	ADVERSE EVENT	6	Cellulitis Status Post Bee Sting	Aug/30/2020 08:00	NO End Date Time: Sep/9/2020 08:00	Repeating Pages

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Swelling]
4.	Start Date Time:	Jul/31/2020 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/1/2020 08:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Pain]
4.	Start Date Time:	Jul/31/2020 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/1/2020 08:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fever]
4.	Start Date Time:	Aug/21/2020 07:00
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Bee Sting]
4.	Start Date Time:	Aug/28/2020 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/28/2020 14:00
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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

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: [Subject has allergy to bee venom]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Anaphylaxis Status Post Bee Sting]
4.	Start Date Time:	Aug/28/2020 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/28/2020 20:00
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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: [Subject with history of allergy to bee venom]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020363634]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Cellulitis Status Post Bee Sting]
4.	Start Date Time:	Aug/30/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/9/2020 08:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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: [Subject with history of allergy to bee venom]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Medication Error

1.	Category:	Not Applicable _____	Comments
2.	Medication Error (Type of Medication Error):	Not Applicable _____	Comments
		[]	
3.	Start Date:	Not Applicable _____	Comments
		//	
4.	Is the medication error still ongoing?	Not Applicable _____	Comments
5.	Latest Action Taken with Study Treatment:	Not Applicable _____	Comments
6.	Was a Concomitant Medication given?	Not Applicable _____	Comments
7.	Was a Non-Drug Treatment given?	Not Applicable _____	Comments
8.	Did the Medication Error cause the subject to be discontinued from the study?	Not Applicable _____	Comments
9.	Was this medication error associated with any adverse events?	Not Applicable _____	Comments
10.	Serious Adverse Event Number: For Pfizer Use Only	Not Applicable _____	Comments
		[]	

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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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.	Date:	Not Applicable _____ //	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1. DELETED	1	CORTICOSTEROIDS	NO	methylprednisolone	125	Repeating Pages

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Deleted, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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

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Concomitant Medications

1.	What is the medication identifier?	[4]	Comments
2.	Category:	CORTICOSTEROIDS	Comments
3.	Concomitant Medications Pre-specified:	NO	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).	[methylprednisolone]	Comments
5.	Dose:	[125]	Comments
6.	Dose Unit:	mg	Comments
7.	Dose Frequency:	ONCE	Comments
8.	Route:	INTRAVENOUS	Comments
9.	Start Date:	Aug/28/2020	Comments
10.	Ongoing?	NO End Date: Aug/28/2020	Comments

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Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Radiation Treatment

1.	Category:	Not Applicable _____	Comments
2.	What is the treatment Identifier?	Not Applicable _____ []	Comments
3.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	Comments
4.	Treatment:	Not Applicable _____ []	Comments
5.	Start Date:	Not Applicable _____ //	Comments
6.	Ongoing?	Not Applicable _____	Comments

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.	Not Applicable	Not Applicable	Repeating Pages

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1.	Transfusion Type:	Not Applicable _____	Comments
2.	Date of Transfusion:	Not Applicable _____ //	Comments

Header Text: c4591001

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

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

Site No: 1140 **Site Name:** (1140) SUNY Upstate Medical University

Subject No: 11401009 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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: 1140 **Site Name:** (1140) SUNY Upstate Medical University

Subject No: 11401009 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

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: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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?	

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (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: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

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: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/16/2020
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: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/18/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/17/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[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, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Stephen Thomas	Approved	Mar-11-2021 11:37:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, StephenThomas, 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.

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
Form	Sep-29-2020 15:07:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
Form	Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1140

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Subject No: 11401009

Subject Initials: ---

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1	Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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2	Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

Header Text: c4591001

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3	Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

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4	Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

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6	Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

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Header Text: c4591001

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Header Text: c4591001

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9	Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1140

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Header Text: c4591001

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Item	Date	User	Comment
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Header Text: c4591001

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Item	Date	User	Comment
2	Sep-29-2020 15:16:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Header Text: c4591001

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1140

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Header Text: c4591001

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Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1140

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Header Text: c4591001

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Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments
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5.f	Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1140

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Item	Date	User	Comment
Form	Sep-29-2020 15:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
1	Sep-29-2020 15:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
2	Sep-29-2020 15:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

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Site No: 1140

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Item	Date	User	Comment
3	Sep-29-2020 15:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Subject No: 11401009

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Item	Date	User	Comment
Form	Sep-29-2020 15:16:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
1	Sep-29-2020 15:16:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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Header Text: c4591001

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Header Text: c4591001

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

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Item	Date	User	Comment
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Header Text: c4591001

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Item	Date	User	Comment
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Header Text: c4591001

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Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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Item	Date	User	Comment
Form	Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
5	Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Subject No: 11401009

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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Item	Date	User	Comment
6	Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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Item	Date	User	Comment
7	Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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Item	Date	User	Comment
8	Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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Subject Initials: ---

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Item	Date	User	Comment
9	Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Generated By: (b) (4)

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Item	Date	User	Comment
10	Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

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Item	Date	User	Comment
Form	Aug-24-2020 10:15:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
1	Aug-24-2020 10:15:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
2	Aug-24-2020 10:15:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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Header Text: c4591001

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Site No: 1140

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Form	Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

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Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
5	Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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Item	Date	User	Comment
6	Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
6	Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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Item	Date	User	Comment
7	Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
7	Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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Item	Date	User	Comment
8	Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
8	Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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Item	Date	User	Comment
9	Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
9	Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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Item	Date	User	Comment
10	Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
10	Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
Form	Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
1	Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
2	Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
3	Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
4	Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
5	Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
6	Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
Form	Aug-24-2020 10:16:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
1	Aug-24-2020 10:16:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Item	Date	User	Comment
2	Aug-24-2020 10:16:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Stephen Thomas	Approved	Mar-11-2021 11:37:53 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, StephenThomas, 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.

(b) (6)	N/A	Feb-10-2021 13:35:36 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Oct-14-2020 11:29:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, StephenThomas, 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.

(b) (6)	N/A	Oct-14-2020 11:03:09 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**Affidavit:**

N/A

Stephen Thomas	Approved	Oct-14-2020 10:42:34 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, StephenThomas, 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.

(b) (6)	N/A	Oct-14-2020 09:47:31 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Oct-13-2020 16:42:57 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, StephenThomas, 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.

(b) (6)	N/A	Oct-13-2020 16:24:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Oct-12-2020 09:51:31 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Affidavit:

By my dated signature below, I, StephenThomas, 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.

(b) (6)	N/A	Oct-12-2020 09:28:54 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Oct-12-2020 08:08:29 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, StephenThomas, 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.

(b) (6)	N/A	Oct-11-2020 21:12:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Oct-11-2020 18:33:14 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Affidavit:

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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.

(b) (6)	N/A	Sep-25-2020 09:19:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Sep-24-2020 08:29:33 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, StephenThomas, 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.

Debbra Scotti	N/A	Sep-24-2020 07:36:43 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Sep-23-2020 16:33:36 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Affidavit:

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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.

(b) (6)	N/A	Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Sep-22-2020 15:05:42 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, StephenThomas, 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.

(b) (6)	N/A	Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Sep-18-2020 15:57:21 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Affidavit:

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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.

(b) (6)	N/A	Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Sep-18-2020 15:54:52 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

(b) (6)	N/A	Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Sep-18-2020 15:53:13 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

(b) (6)	N/A	Sep-18-2020 09:58:27 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Sep-17-2020 20:10:04 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, StephenThomas, 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.

(b) (6)	N/A	Sep-17-2020 15:32:25 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Sep-14-2020 15:17:15 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Affidavit:

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jul-31-2020 12:20:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:20:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (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: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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I. Consent Was:

Date	Location	User	Value	Reason
Jul-31-2020 12:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jul/31/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Subject ID

Date	Location	User	Value	Reason
Jul-31-2020 12:20:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11401009	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jul-31-2020 12:20:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1979	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-10-2020 09:27:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Page added hence closing query
Aug-06-2020 12:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	DM Query: Reactogenicity Diary left blank. Please provide missing data or else clarify.
Jul-31-2020 12:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jul/31/2020	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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I.a

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Inclusion Number: Criterion Description: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) Criterion met?: Criterion ID: (Formerly Pfizer only): IN01A00	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
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I.a Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

I.b

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Inclusion Number: 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	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

			Criterion ID : (For Pfizer use only):	
			IN02A00	

1.b Inclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 2	Initial Entry

1.b Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

1.c

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<p>Data Entry:</p> <p>Inclusion Number:</p> <p>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</p> <p>Criterion Met?: YES</p> <p>Criterion ID: IN03A00</p> <p>Use Only: (For Pfizer use only):</p>	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44***I.c Inclusion Number:***

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Inclusion Number:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

			<p>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</p> <p>Criterion Met?: YES</p> <p>Criterion ID: IN04A00</p> <p>Use Only: (For Pfizer use only):</p>	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**1.d Inclusion Number:**

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 4	Initial Entry

1.d Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

			<p>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</p> <p>Criterion met?:</p> <p>Criterion ID: EX01A00</p> <p>Filter: (F or Pfizer use only)</p>
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry
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2.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Exclusi 2 on Nu mber: Criteria Known infection with on Desc human immunodefici ription: ency virus (HIV), hep atitis C virus (HCV), or hepatitis B virus (HBV) Criteria NO on met ?: Criteria EX02A00 on ID: (For Pfi zer use only):	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**2.b Exclusion Number:**

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

			<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 ID: NO</p> <p>Criterion ID: EX03A00</p> <p>Criterion ID: (For Pfizer use only):</p>	
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**2.c Exclusion Number:**

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Exclusion Number: 4	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

			Criterion D Receipt of medication intended to prevent COVID-19 Criterion m NO et?: Criterion I EX04A00 D: (For Pfizer use only):	
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2.d Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX04A00	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.e

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Exclusion Number: Criteria: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination Criterion met?: Criteria ID: EX08A00 (For Pfizer use only):	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**2.e Exclusion Number:**

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

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			<p>Criterion Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p>Criterion ID: NO</p> <p>Criterion ID: EX10A00</p> <p>Criterion ID: (For Pfizer use only):</p>	
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**2.f Exclusion Number:**

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Exclusion Number: 11	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1140**Subject No:** 11401009**Generated By:** (b) (4)**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1140) SUNY Upstate Medical University**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44

			Criterion Description: Women who are pregnant or breastfeeding Criterion met?: NO Criterion ID: EX11A00 (For Pfizer use only):	
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject Initials: ---

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Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: (For Pfizer use only): EX12A00	Initial Entry
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.i

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Exclusion Number: 13 Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids Criterion met?: NO Criterion ID: (For use only): EX13A01	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.i Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

			<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 ID: NO</p> <p>Criterion ID: EX14A01</p> <p>Criterion ID: (For Pfizer use only):</p>	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.j Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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2.k

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number:</p> <p>Criterion Description: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation</p> <p>Criterion met?: NO</p> <p>Criterion ID: EX15A01 (For Pfizer use only)</p>	Initial Entry

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Header Text: c4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.k Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Participation in other studies in volving study intervention with in 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Exclusio 17 n Number: er:	Initial Entry

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Header Text: c4591001

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Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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			<p>Criterion Description: Previous participation in other studies involving study intervention containing lipid nanoparticles</p> <p>Criterion met?: NO</p> <p>Criterion ID: (Former Pfizer only): EX16A01</p>	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

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Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

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2.l Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> 17	Initial Entry

2.l Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.l Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Exclusion Number:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject Initials: ---

Generated By: (b) (4)

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			<p>Crite Investigator site staff o ri r Pfizer employees dire on ctly involved in the con Descr duct of the study, site st ption : aff otherwise supervise d by the investigator, a nd their respective fam ily members</p> <p>Crite NO ri on met?:</p> <p>Crite EX21A01 ri on I D: (F or Pfi zer us e only):</p>	
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

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Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

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2.m Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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.m Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:21:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jul-31-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jul/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jul-31-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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I.a

Date	Location	User	Value	Reason
Jul-31-2020 12:22:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Te Asthma rm: Start Date: Nov/1/19 85 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:22:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:22:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Asthma	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 12:22:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Nov/1/1985	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 12:22:33 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Time (US & Canada)

1.b

Date	Location	User	Value	Reason
Jul-31-2020 12:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Ter Gout m: Start Date: Sep/1/201 3 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:22:53 (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
Jul-31-2020 12:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Gout	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 12:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sep/1/2013	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 12:22:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

I.c

Date	Location	User	Value	Reason
Jul-31-2020 15:30:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Line/MH Number: 3 Medical History Term: Allergy to cats Start Date: Aug/1/1988 Ongoing: YES	Transcription Error
Jul-31-2020 12:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Allergy to cats, bees, shrimp Start Date: Aug/1/1988 Ongoing: YES	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

I.c Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 16:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Cl osed	Discrepancy has been closed.
Jul-31-2020 16:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Op ened	Multiple concepts in the term ALLERGY TO CATS, BEES, SHRIMP. Split the term into ALLERGY TO CATS and ALLERGY TO BEES and ALLERGY TO SHRIMP and report as 3 separate entries. Thank you.
Jul-31-2020 15:30:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry : Allergy to c ats	Transcription Error
Jul-31-2020 12:23:23 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry : Allergy to c	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1140
Subject No: 11401009
Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1140) SUNY Upstate Medical University
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:44

Eastern Time (US & Canada)			ats, bees, sh rimp
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I.c Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 12:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/1/1988	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 12:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-07-2020 10:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Line/MH Number: Medical History Term: Start Date: Jun/1/1997 Ongoing: NO End Date: : Jun/1/1997	entry deleted as per query request (DELETED)
Aug-07-2020 08:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: Jun/1/1997	Removed as per query

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

			Ongoing: NO End Date : Jun/1/1997	
Jul-31-2020 12:24:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Wisdom teeth extraction Start Date: Jun/1/1997 Ongoing: NO End Date: Jun/1/1997	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 10:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	entry deleted as per query request (DELETED)
Aug-07-2020 08:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Removed as per query
Jul-31-2020 12:24:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 10:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 2: Closed	deleted
Aug-07-2020 10:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: :	entry deleted as per query request (DELETED)
Aug-07-2020 10:08:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Closed	Response satisfies query
Aug-07-2020 09:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Opened	Null Term: Verbatim term must not be null/blank.

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1140
Subject No: 11401009
Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1140) SUNY Upstate Medical University
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:44

Canada)				
Aug-07-2020 08:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Removed as per query
Aug-07-2020 08:48:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Removed as per query
Aug-03-2020 09:32:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Op ened	Please note teeth extractions are not considered relevant procedures. Please can you remove as appropriate. Thanks
Jul-31-2020 12:24:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Wisd om teet h extr action	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 10:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jun/1/1997	entry deleted as per query request (DELETED)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Jul-31-2020 12:24:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jun/1/1997	Initial Entry
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I.d Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 10:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO End Date: Jun/1/1997	entry deleted as per query request (DELETED)
Jul-31-2020 12:24:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO End Date: Jun/1/1997	Initial Entry

I.e

Date	Location	User	Value	Reason
Jul-31-2020 15:31:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 5 : Medical History T Allergy to b erm: ees Start Date: Aug/1/1988 Ongoing: YES	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

I.e Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 15:31:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 15:31:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Allergy to bees	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 15:31:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/1/1988	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 15:31:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Jul-31-2020 15:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Allergy to shrimp Start Date: Aug/1/1988 Ongoing: YES	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

I.f Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 15:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 15:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Allergy to shrimp	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 15:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/1/1988	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 15:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Jul-31-2020 15:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History: allergy to penicillin Term: Start Date: Aug/1/1988 Ongoing: YES	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

I.g Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 15:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 15:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: allergy to penicillin	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

1.g Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 15:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/1/1988	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 15:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jul/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 224.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-07-2020 10:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	lb is selected for weight unit, then in is expected to be selected for Height unit. Please check and update data as appropriate.
Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-07-2020 10:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

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Generated Time (GMT): 29-Mar-2021 11:44

Aug-07-2020 10:08:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Height 72.36 is outside of Normal Range 140 - 198 for cm or 55 - 80 for in.
Aug-07-2020 10:08:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 72.36	Units converted as per query request
Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 183.8	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-07-2020 10:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: in	Units converted as per query request
Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-07-2020 10:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.2	Units converted as per query request
Aug-07-2020 10:08:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Units converted as per query request
Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Record Identifier: 1 Temperature: 97.9 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 97.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Jul-31-2020 12:25:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Jul-31-2020 12:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jul/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jul-31-2020 12:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 40104	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

Date	Location	User	Value	Reason
Jul-31-2020 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-31-2020 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-05-2020 13:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-04-2020 05:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DQ: Please review the 'Sample Collected?' is reported as Yes however no any barcodes are entered. Kindly review and correct the data as appropriate. Thank you.
Jul-31-2020 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

				as appropriate.
Jul-31-2020 12:26:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Jul/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-05-2020 13:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG57C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 13:57:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPG57C	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-05-2020 13:57:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG57D	Transcription Error
Aug-05-2020 13:57:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG57C	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.b Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 13:57:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> BPG57D	Transcription Error
Aug-05-2020 13:57:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> BPG57C	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-05-2020 13:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNB416	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 13:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> BNB416	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-05-2020 13:58:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNB417	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 13:58:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> BNB417	Initial Entry

5.e

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Date	Location	User	Value	Reason
Aug-05-2020 13:58:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BNB418	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 13:58:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BNB418	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

Date	Location	User	Value	Reason
Jul-31-2020 12:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-31-2020 12:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-05-2020 12:00:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-04-2020 05:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DQ: Please review the 'Sample Collected?' is reported as Yes however no any barcodes are entered. Kindly review and correct the data as appropriate. Thank you.
Jul-31-2020 12:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

				as appropriate.
Jul-31-2020 12:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Jul/31/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Aug-05-2020 13:59:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-05-2020 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: UPDATED PER SD	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-05-2020 12:00:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BNB419	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 12:00:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BNB419	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jul-31-2020 12:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jul-31-2020 12:26:44 (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-31-2020 12:26:44 (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-31-2020 12:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jul/31/2020 09:28	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jul-31-2020 12:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Jul-31-2020 12:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Jul-31-2020 12:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jul-31-2020 12:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 12:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-07-2020 09:18:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E- DIARY COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-21-2020 09:43:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:30**Site No:** 1140**Subject No:** 11401009**Generated By:** (b) (4)**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1140) SUNY Upstate Medical University**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic s N ymptoms present on the O last day the Subject Diar y was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:30

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic s NO ymptoms present on the last day the Subject Dia ry was completed?:	Initial Entry
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2.b Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM
RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**2.c Symptom:**

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 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
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic s N ymptoms present on the O last day the Subject Dia ry was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.e

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on t he last day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on t he last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.f Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WORS ENED M USCLE PAIN Were fever or syst emic symptoms pr esent on the last da y the Subject Diar y was completed?: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.g Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEW OR WORSENERED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENERED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.h Symptom:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEW OR WORSENER JOIN T 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
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (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
Aug-21-2020 09:44:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE : DN ES S	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

			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
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Injection Site Reaction SW :: ELL ING Were injection site reactions present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Aug-21-2020 09:43:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1140**Subject No:** 11401009**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1140) SUNY Upstate Medical University**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Aug-21-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/20/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-21-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Record Identifier: r:: Temperature: 98.7 Temperature Unit: it: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 98.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:30	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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

(b) (4), (b) (6)

F

2.a Temperature Location:

Date	Location	User	Value	Reason
Aug-21-2020 09:43:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-21-2020 09:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-21-2020 09:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-21-2020 10:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 09:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-21-2020 09:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Aug-21-2020 10:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPYZLR	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 10:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPYZLR	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-21-2020 09:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-21-2020 09:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-21-2020 09:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-21-2020 09:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/20/2020 14:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-21-2020 09:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Aug-21-2020 09:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Aug-21-2020 09:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-21-2020 09:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 09:44:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-25-2020 07:46:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-24-2020 09:32:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Barcode for self-nasal swab updated in Covid Illness visit form
Sep-23-2020 06:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thanks for response. Please confirm if SCF is submitted for this, else clarify.
Sep-22-2020 12:59:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Nasal self swab was not done in relation to this incident.
Sep-22-2020 10:28:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Nasal Self Swab barcode RW86831 was received by the lab for COVID A Visit. Please review and update accordingly or submit an updated SCF.
Sep-17-2020 15:32:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sep/17/2020	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the la O st day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic s ymptoms present on the last day the Subject Diar y was completed?:	Initial Entry
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2.b Symptom:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic NO symptoms present on th e last day the Subject Di ary was completed?:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

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Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.c Symptom:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: CH IL LS Were fever or systemic s N ymptoms present on the l O ast day the Subject Diary was completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.e

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic NO symptoms present on th e last day the Subject Di ary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic s NO ymptoms present on the last day the Subject Dia ry was completed?:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.f Symptom:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.g Symptom:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEW OR WORSENER MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSENER JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.h Symptom:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEW OR WORSENERD 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
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ES S	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

			Were injection site reactions present on the last day the Subject Diary was completed?:	
--	--	--	---	--

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW : ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 15:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 15:33:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-17-2020 15:33:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-18-2020 09:58:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-18-2020 06:07:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 15:33:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 15:33:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Time (US & Canada)			Date of Collection:	
			Sep/17/2020	

5.a

Date	Location	User	Value	Reason
Sep-18-2020 09:58:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPYZ56	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-18-2020 09:58:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPYZ56	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-18-2020 10:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BNWXLW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-18-2020 10:09:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BNWXLW	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-18-2020 10:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BNWXLX	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.c Sample ID

Date	Location	User	Value	Reason
Sep-18-2020 10:14:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BNWXLX	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-18-2020 10:15:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BNWXLY	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-18-2020 10:15:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BNWXLY	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-11-2021 14:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Feb/11/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

Date	Location	User	Value	Reason
Feb-11-2021 14:41:48 (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-11-2021 14:41:48 (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-12-2021 13:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-12-2021 06:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 14:41:48 (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-11-2021 14:41:48 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Time (US & Canada)			Date of Collection:	
			Feb/11/2021	

5.a

Date	Location	User	Value	Reason
Feb-12-2021 13:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BRFJD8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-12-2021 13:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BRFJD8	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-12-2021 13:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BSGRDP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-12-2021 13:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BSGRDP	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-12-2021 13:56:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BSGRDR	Initial Entry

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Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

5.c Sample ID

Date	Location	User	Value	Reason
Feb-12-2021 13:56:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BSGRDR	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 17:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-13-2020 16:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Answered	Convalescent visit performed and data entered
Oct-02-2020 15:25:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	Clinical Query: Pending completion of convalescent visit.
Oct-01-2020 13:12:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Sep-30-2020 10:04:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Answered	We will reach out to the subject for the convalescent plasma visit.
Sep-30-2020 09:58:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Answered	COVID TEST data has been updated
Sep-28-2020 15:12:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical Query: Per protocol, CONVALESCENT Visit must take place 28 to 35 days after COVID Illness Visit, please clarify if CONVA visit has been completed. If not, please complete

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

				as soon as possible.
Sep-24-2020 19:57:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical Query: Per CRF CRs Section 8.29, please complete COVID TEST, SWAB PFE, HLTHCARE, and ILL POTEN forms.
Sep-23-2020 15:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-23-2020 15:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Sep-23-2020 15:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Sep-23-2020 15:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/21/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Sep-23-2020 15:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Assessment:

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/21/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/21/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 15:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-23-2020 15:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resol ved: Aug/24/2020	Transcription Error
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Last Symptom Resolved date is a future date compared to when it was entered. Please correct.
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resol ved:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

			Sep/24/2020	
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4.a

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCRE : ASSED COUGH Symptom NO Present:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

4.b Symptoms:

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

4.d

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1140**Subject No:** 11401009**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1140) SUNY Upstate Medical University**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44**4.e Symptoms:**

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUS CLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom NEW LOSS OF T s: ASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR S MELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -
eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**4.h Symptoms:**

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Sep-23-2020 15:11:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Date	Location	User	Value	Reason
Sep-30-2020 09:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Sep-30-2020 09:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/21/2020	Initial Entry
Sep-29-2020 15:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Sep-30-2020 09:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry
Sep-29-2020 15:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Sep-30-2020 09:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry
Sep-29-2020 15:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44

Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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4. Assay Code and Description:

Date	Location	User	Value	Reason
Sep-30-2020 09:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYN DROME CORONAVIRUS 2	Initial Entry
Sep-29-2020 15:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Sep-30-2020 09:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry
Sep-29-2020 15:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Sep-30-2020 09:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: OTHER	Initial Entry
Sep-29-2020 15:07:56	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Sep-30-2020 09:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry
Sep-29-2020 15:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Sep-29-2020 15:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Sep-30-2020 09:47:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Rheonix COVID-19 MDx assay	Initial Entry
Sep-29-2020 15:07:56 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Time (US & Canada)				
Sep-29-2020 15:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1140**Subject No:** 11401009**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1140) SUNY Upstate Medical University**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-23-2020 15:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 15:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 15:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 15:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 15:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Sep-23-2020 15:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: RW86831	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-23-2020 15:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: RW86831	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-29-2020 15:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-29-2020 15:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-29-2020 15:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Sep-29-2020 15:02:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: TELEMED CONDUCTED VI A PHONE	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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I.a

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Type of Practitioner SPECIA : LIST Occurrence of Visit NO s or Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Type of Practitio EMERGEN ner: CY ROOM Occurrence of V NO isits or Contacts :	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

I.d

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATIO N	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits o NO r Contacts:	Initial Entry

I.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

I.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Date	Location	User	Value	Reason
Sep-29-2020 15:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Sep-29-2020 15:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Sep-29-2020 15:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Sep-29-2020 15:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Sep-29-2020 15:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Sep-29-2020 15:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Date	Location	User	Value	Reason
Sep-29-2020 15:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Sep-29-2020 15:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLN ESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Sep-29-2020 15:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 08:52:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-11-2020 21:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-11-2020 21:12:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 1	Transcription Error
Sep-30-2020 14:59:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: As subject is symptomatic, per CCG's toxicity grade from 1-5 should be entered. Please update.
Sep-29-2020 15:11:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 0	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Sep-29-2020 15:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Sep-29-2020 15:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Sep-29-2020 15:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-29-2020 15:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sponsor-Defined I Not Appli dentifier: cable Test:: Not Appli cable	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/21/2020
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Subject No: 11401009
Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History
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Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.b

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

5.b Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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(UTC-05:00) Eastern
Time (US & Canada)

(b) (4), (b) (6)

Sponsor-Defined Identifier: Not Applicable

Test: Not Applicable

Result: Not Applicable

Not Done: Not Applicable

Lab Normal Range: Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Site Name: (1140) SUNY Upstate Medical University

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:27

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
- eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:27

Site No: 1140

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- eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

5.d Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

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Form Version: 30-Jul-2020 21:27

Site No: 1140

Subject No: 11401009

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable
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Visit: POT_COVID_ILL 1 - Unscheduled
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Form Version: 30-Jul-2020 21:27

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Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.e Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
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5.e Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Site No: 1140

Subject No: 11401009

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable
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Visit: POT_COVID_ILL 1 - Unscheduled
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Site No: 1140

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Subject No: 11401009

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Generated Time (GMT): 29-Mar-2021 11:44

5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form Version: 30-Jul-2020 21:27

Site No: 1140

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Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

5.g Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:13:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: LOCAL LABORATORY DATA - REPEATING Hematology -
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Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sponsor-Defined I Not Appli dentifier: cable Test:: Not Appli cable	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Aug/21/2020
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Site No: 1140
Subject No: 11401009
Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
Form Status: Data Complete, Frozen, Verified
Site Name: (1140) SUNY Upstate Medical University
Subject Initials: ---
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Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.b

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Form: LOCAL LABORATORY DATA - REPEATING Hematology -
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Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

5.b Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

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(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
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5.d

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable
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Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

5.e Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

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Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

5.g Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

5.h Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
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Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Sponsor-Defined Identifier: Not Applicable Test: Not Applicable Result: Not Applicable Not Done: Not Applicable Lab Normal Range: Not Applicable
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
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Site Name: (1140) SUNY Upstate Medical University

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

5.j Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Sep-29-2020 15:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

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1. Date:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 15:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Record Identifier:: Not Ap plicable Systolic:: Not Ap plicable Diastolic:: Not Ap plicable Respiratory Rate in Not Ap respirations/minute: plicable Heart Rate in beats/ Not Ap minute: plicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.a Diastolic:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail
History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Record Identify Not Applica r:: ble Oxygen Saturati Not Applica on: ble	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Sep-29-2020 15:14:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Form: OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Sep-29-2020 15:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Sep-29-2020 15:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Sep-29-2020 15:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1140**Subject No:** 11401009**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS -
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1140) SUNY Upstate Medical University**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Sep-29-2020 15:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Sep-29-2020 15:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Sep-29-2020 15:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Sep-29-2020 15:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Sep-29-2020 15:16:26 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
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Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Time (US & Canada)

6. Ongoing?

Date	Location	User	Value	Reason
Sep-29-2020 15:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled
Visit on Aug/21/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Assessment:

Date	Location	User	Value	Reason
Sep-29-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Sep-29-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Sep-29-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Sep-29-2020 15:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF
Visit on Oct/13/2020 Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 16:24:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Oct/13/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-13-2020 16:24:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Visit on Oct/13/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-13-2020 16:24:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-13-2020 16:24:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-14-2020 09:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 16:24:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-13-2020 16:24:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Visit on Oct/13/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44

Oct-14-2020 09:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPYZCD	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 09:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPYZCD	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 09:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG5X4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 09:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPG5X4	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 11:03:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG5XL	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 11:03:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPG5XL	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-25-2020 09:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sep/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-25-2020 09:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-25-2020 09:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Date	Location	User	Value	Reason
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Date	Location	User	Value	Reason
Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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

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Date	Location	User	Value	Reason
Aug-28-2020 09:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Deleted	same as the eDiary entry
Aug-24-2020 10:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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

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Date	Location	User	Value	Reason
Sep-21-2020 14:41:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Deleted	Deleting AE per request of sponsor
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Category:

Date	Location	User	Value	Reason
Aug-24-2020 10:13:03 (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
Aug-24-2020 10:13:03 (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
Aug-26-2020 14:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-26-2020 09:36:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	This is to confirm that AE: Injection site swelling is same as the e-Diary swelling occurrence reported.
Aug-25-2020 12:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	e-Diary: AE 'Injection site swelling' seems to be same as e-Diary Swelling Occurrence reported. Please reconcile or confirm in the query response as appropriate.

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

				Thanks
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Injection Site Swelling	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jul/31/2020 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/1/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 10:13:03	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

(b) (4), (b) (6)

RECOVERED/RESOLVED

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

Date	Location	User	Value	Reason
Aug-24-2020 10:13:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Category:

Date	Location	User	Value	Reason
Aug-24-2020 10:14:00 (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
Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Aug-26-2020 14:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-26-2020 09:38:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	This is to confirm that the AE: Injection site pain is same as the eDiary pain at injection site occurrence reported.
Aug-25-2020 12:57:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	e-Diary: AE 'Injection site pain' seems to be same as e-Diary Pain at Injection Site Occurrence reported. Please reconcile or confirm in the

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

				query response as appropriate. Thanks
Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Injection Site Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jul/31/2020 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/1/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Aug-24-2020 10:14:00 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Time (US & Canada)

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
Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-24-2020 10:15:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
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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, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Aug-24-2020 10:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Aug-24-2020 10:14:57 (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
Aug-24-2020 10:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Aug-31-2020 10:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Data deleted
Aug-28-2020 09:02:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	same as the eDiary entry
Aug-28-2020 07:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	e-Diary: AE 'Fever' seems to be same as e-Diary Fever Occurrence reported. Please reconcile or confirm in the query response as appropriate. Thanks
Aug-24-2020 10:14:57	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Subject No: 11401009

Generated By: (b) (4)

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

(b) (4), (b) (6)

Fever

4. Start Date Time:

Date	Location	User	Value	Reason
Aug-24-2020 10:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/21/2020 07:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-24-2020 10:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-24-2020 10:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Aug-24-2020 10:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

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

Date	Location	User	Value	Reason
Aug-24-2020 10:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Aug-24-2020 10:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-24-2020 10:15:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-24-2020 10:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-24-2020 10:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Aug-24-2020 10:14:57 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RE	Initial Entry

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Time (US & Canada)			SOLVED	
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Aug-24-2020 10:14:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1140**Subject No:** 11401009**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Deleted, Locked, Frozen, Verified**Site Name:** (1140) SUNY Upstate Medical University**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44

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

[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Sep-18-2020 15:54:29 (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
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Bee Sting	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/28/2020 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/28/2020 14:00	Initial Entry

Header Text: c4591001

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Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-22-2020 06:59:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event inactivated
Sep-21-2020 12:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	SAE has been reported to Pfizer and SAE forms completed and faxed to Pfizer
Sep-20-2020 10:52:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: Bee Sting(Onset date:28-AUG-2020) is not reported on SAE Report Form but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF

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Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Bee Sting: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Is this serious event associat ed with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event requir e or prolong hospitalization? NO Did this serious event result in persistent or significant di sability/incapacity? NO Is this serious event life thre atening? YES Other medically important s erious event NO	Initial Entry

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

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Header Text: c4591001

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Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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

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

Date	Location	User	Value	Reason
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatm ent(s), this event is due to: OTHER <i>If Other, specify:</i> Subject has allergy to be e venom	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-21-2020 22:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	event deleted.
Sep-21-2020 12:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-21-2020 12:42:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Transcription Error
Sep-21-2020 12:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Opened	Both vaccinations were given, please update to Not Applicable.

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Generated By: (b) (4)

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Subject Initials: ---

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Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: DRUG WITHDRAWN	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Sep-18-2020 15:54:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (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
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Anaphylaxis Status Post Bee S ting	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/28/2020 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/28/2020 20:00	Initial Entry

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Site Name: (1140) SUNY Upstate Medical University

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6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-22-2020 06:55:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	subject id updated in SDB
Sep-21-2020 12:43:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	Spontaneous coronary artery dissection is for a different patient.
Sep-21-2020 06:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020363609 worsening of spontaneous coronary artery dissection(onset date:28Aug2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Sep-21-2020 06:00:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event recorded in SDB

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<p>Sep-20-2020 10:53:26 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Opened</p>	<p>SAE RECON:Anaphylaxis Status Post Bee Sting(Onset date:28AUG2020) is not reported on SAE Report Form but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF</p>
<p>Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto query (autoquery)</p>	<p>Query 1: Candidate</p>	<p>For AE Anaphylaxis Status Post Bee Sting: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.</p>
<p>Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6) (b) (4), (b) (6)</p>	<p>Data Entry: YES Is this serious event as sociated with congenit al anomaly or birth def ect? NO Did this serious event r esult in death? NO Did this serious event r equire or prolong hosp italization? NO Did this serious event r esult in persistent or si gnificant disability/inc apacity?</p>	<p>Initial Entry</p>

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			NO	
			Is this serious event life threatening?	
			YES	
			Other medically important serious event	
			NO	

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

Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Subject with history of allergy to bee venom	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-22-2020 06:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Action taken updated in SDB to not applicable. issue resolved

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1140**Subject No:** 11401009**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1140) SUNY Upstate Medical University**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44

Sep-21-2020 12:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Not applicable is checked here because there is not a "dose not changed" option to check. The only other option is that drug was withdrawn, which would not apply to this instance.
Sep-21-2020 06:05:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020363634 ,action taken was reported as NOT APPLICABLE in AE CRF while DOSE NOT CHANGED in Safety database.Please confirm. If safety update is required, please submit a f
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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

Date	Location	User	Value	Reason
Sep-18-2020 15:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-21-2020 06:02:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (6)	Data Entry: 2020363634	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

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Generated Time (GMT): 29-Mar-2021 11:44

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1. Category:

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (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
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Cellulitis Status Post Bee Sting	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/30/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/9/2020 08:00	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

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

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatm ent(s), this event is due to: OTHER If Other, specify: Subject with history of al lergy to bee venom	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Sep-18-2020 15:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Category:

Date	Location	User	Value	Reason
Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Medication Error (Type of Medication Error):

Date	Location	User	Value	Reason
Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Is the medication error still ongoing?

Date	Location	User	Value	Reason
Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Did the Medication Error cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Was this medication error associated with any adverse events?

Date	Location	User	Value	Reason
Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Aug-24-2020 10:15:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Aug-24-2020 10:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Aug-24-2020 10:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Aug-24-2020 10:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Aug-24-2020 10:15:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Aug-24-2020 10:15:48 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
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Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Form Status:

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

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Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-12-2020 09:28:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Deleted	New Information
Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
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Subject Initials: ---

Generated By: (b) (4)

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry
Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: CORTICOSTEROIDS	Initial Entry
Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry
Sep-23-2020 14:54:11 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry

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Site No: 1140

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Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

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Time (US & Canada)				
Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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
Oct-13-2020 16:49:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-12-2020 09:28:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Oct-01-2020 05:21:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	ClinQuery: methylprednisolone:Please note this medication doesn't meet the dose/duration criteria in order to be listed in this log (6.5.1 of protocol). Please remove as appropriate. Thanks
Sep-23-2020 15:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Deleted, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44***** THIS REPEATING FORM HAS BEEN DELETED *****

Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: methylprednisolone	Initial Entry
Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-22-2020 16:53:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Subject received Methylprednisolone while in the emergency room, per protocol if the steroids >20mg was given for more than 14 days – that needs to be added to the con med CRF. Please revise accordingly. Thank you.
Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Sep-23-2020 14:56:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 125	Transcription Error
Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 125mg	Initial Entry
Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Aug-24-2020 10:16:00	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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

(b) (4), (b) (6)

Not Applicable

6. Dose Unit:

Date	Location	User	Value	Reason
Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> mg	Initial Entry
Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Sep-23-2020 14:57:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> ONCE	Transcription Error
Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> PRN	Initial Entry
Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

8. Route:

Date	Location	User	Value	Reason
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Deleted, Frozen, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44***** THIS REPEATING FORM HAS BEEN DELETED *****

Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: INTRAVENOUS	Initial Entry
Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/28/2020	Initial Entry
Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Aug-24-2020 10:16:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 14:55:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO End Date: Aug/28/2020	Initial Entry
Sep-23-2020 14:54:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Aug-24-2020 10:16:00 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Time (US & Canada)				
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Category:

Date	Location	User	Value	Reason
Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. What is the treatment Identifier?

Date	Location	User	Value	Reason
Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Aug-24-2020 10:16:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401009

Generated By: (b) (4)

Form: TRANSFUSIONS - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Transfusion Type:

Date	Location	User	Value	Reason
Aug-24-2020 10:16:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Date of Transfusion:

Date	Location	User	Value	Reason
Aug-24-2020 10:16:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 15:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Dec/16/2020	Changed Information
Feb-10-2021 13:36:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Date	Location	User	Value	Reason
Feb-10-2021 13:36:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-10-2021 13:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Dec/18/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-10-2021 13:35:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (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: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Subject Status

Date	Location	User	Value	Reason
Sep-25-2020 09:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jul-31-2020 12:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jul-31-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Sep-25-2020 09:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/17/2020	Initial Entry
Jul-31-2020 12:25:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/31/2020	Initial Entry
Jul-31-2020 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/31/2020	Initial Entry

090177e196ae30f9\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-09-2020 09:29:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry