

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: COHORT SELECTION

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](#)

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 Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jul/29/2020
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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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11401002]
2.	Birth Date:	(b) (6) /1956
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

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/29/2020
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 17-Jul-2020 21:53**Site No:** 1140**Subject No:** 11401002**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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	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

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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.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
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

090177e196ae30f7\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: 11401002

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/29/2020
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: 11401002

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:	[Hypertension]
	Start Date:	UNK/UNK/1979
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Spontaneous Coronary artery dissection]
	Start Date:	Dec/7/2019
	Ongoing:	NO End Date: Dec/31/2019
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	UNK/UNK/1974
	Ongoing:	YES

090177e196ae30f7\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: 11401002

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:	[Osteopenia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/29/2020	
2.	Weight:	Not Done _____ []	Comments
3.	Unit:	Not Done _____ []	Comments
4.	Height:	Not Done _____ []	Comments
5.	Unit:	Not Done _____ []	Comments
6.	Body Mass Index:	[]	

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jul/29/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

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/29/2020
2.	Randomization Number:	[220241]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPG56X]
5.b	Sample ID	[BPG56Y]
5.c	Sample ID	[BPG56Z]
5.d	Sample ID	[BNB40C]
5.e	Sample ID	[BNB40D]
5.f	Sample ID	[BNB40F]

090177e196ae30f7\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: 11401002

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/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BNB408]
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090177e196ae30f7\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: 11401002

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/29/2020 14:44
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

090177e196ae30f7\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: 11401002

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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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

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/17/2020
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: 11401002

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
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

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:	Aug/17/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Done //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

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

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

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/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	[BPYZG4]
5.b	Sample ID	[]

090177e196ae30f7\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: 11401002

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/17/2020 09:51
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

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

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: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae30f7\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: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

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: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

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: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

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 Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

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	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

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 Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

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	[]
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Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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 Illness Visit

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

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

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

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

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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: 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: 11401002

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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

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](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Sep/17/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	WITHDRAWAL BY SUBJECT
4.	Specify Status:	[Subject no longer wanted to participate after experiencing a spontaneous coronary artery dissection]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

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](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Sep/17/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	WITHDRAWAL BY SUBJECT
4.	Specify Status:	[Subject no longer wanted to participate after experiencing a spontaneous coronary artery dissection]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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. DELETED	ADVERSE EVENT	1	Pain at Injection site	Jul/30/2020 UNK:UNK	NO End Date Time: Aug/1/2020 UNK:UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	Diarrhea	Jul/31/2020 UNK:UNK	NO End Date Time: Jul/31/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Spontaneous coronary artery dissection	Aug/28/2020 UNK:UNK	NO End Date Time: Aug/28/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Myocardial Ischemia	Aug/28/2020 UNK:UNK	NO End Date Time: Aug/28/2020 UNK:UNK	Repeating Pages

090177e196ae30f7\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: 11401002

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 ***

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pain at Injection site]
4.	Start Date Time:	Jul/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/1/2020 UNK:UNK
6.	Toxicity Grade:	±
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae30f7\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: 11401002

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 ***

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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

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 ***

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Diarrhea]
4.	Start Date Time:	Jul/31/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jul/31/2020 UNK:UNK
6.	Toxicity Grade:	+
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae30f7\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: 11401002

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 ***

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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Spontaneous coronary artery dissection]
4.	Start Date Time:	Aug/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/28/2020 UNK:UNK
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? YES 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
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: [History of coronary artery dissection]

090177e196ae30f7\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: 11401002

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	[2020363609]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Myocardial Ischemia]
4.	Start Date Time:	Aug/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/28/2020 UNK:UNK
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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Suffered some myocardial ischemia at the time of dissection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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	[]

090177e196ae30f7\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: 11401002

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

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

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

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

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

090177e196ae30f7\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: 11401002

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: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ []	Comments
5.	Date:	Not Applicable _____ //	Comments

090177e196ae30f7\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: 11401002

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.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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

Concomitant Medications

1.	What is the medication identifier?	Not Applicable _____ []	Comments
2.	Category:	Not Applicable _____	Comments
3.	Concomitant Medications Pre-specified:	Not Applicable _____	Comments
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ []	Comments
5.	Dose:	Not Applicable _____ []	Comments
6.	Dose Unit:	Not Applicable _____	Comments
7.	Dose Frequency:	Not Applicable _____	Comments
8.	Route:	Not Applicable _____	Comments
9.	Start Date:	Not Applicable _____ //	Comments
10.	Ongoing?	Not Applicable _____	Comments

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

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: 11401002

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

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: RADIATION TREATMENT

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](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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

090177e196ae30f7\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: 11401002

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

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: TRANSFUSIONS

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](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

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: 11401002

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: 11401002

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: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Lab Urinalysis

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

Lab Result

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

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

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: 11401002

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?	

090177e196ae30f7\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: 11401002

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: 11401002

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: 11401002

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: 11401002

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:** 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: 11401002

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

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: 11401002

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

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

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Not Applicable	Comments
----	---	----------------	--------------------------

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Not Applicable _____ //	Comments
2.	Primary Reason for Unblinding:	Not Applicable _____	Comments

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Locked, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	Sep/17/2020
----	------------------------------	-------------

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Death Details

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	Comments
----	---	-------------------------------	--------------------------

Cause of Death

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ []

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

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	DISCONTINUED
2.	Subject Status Date	Sep/17/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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: 11401002

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 11:26:51 (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.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - Comments

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](#)

Item	Date	User	Comment
Form	Aug-11-2020 11:27:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	vital signs that not collected as per CRF completion requirement section 4.7

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - Comments

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](#)

Item	Date	User	Comment
2	Aug-17-2020 11:23:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Data not collected in error. Not Done
2	Aug-11-2020 10:31:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	data not collected due to error. will be collected at the following visit

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - Comments

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](#)

Item	Date	User	Comment
3	Aug-18-2020 13:08:28 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Data not collected in error <hr/> Not Done

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - Comments

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](#)

Item	Date	User	Comment
4	Aug-17-2020 11:23:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Data not collected in error. Not Done
4	Aug-11-2020 10:32:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Data not collected due to error. will be collected at the following visit

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - Comments

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](#)

Item	Date	User	Comment
5	Aug-18-2020 13:08:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Data not collected in error <hr/> Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
3	Aug-17-2020 13:37:02 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject with documented hysterectomy. Not of childbearing potential. No pregnancy test necessary. <hr/> Not Done

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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](#)

Item	Date	User	Comment
Form	Sep-22-2020 12:56:17 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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](#)

Item	Date	User	Comment
1	Sep-22-2020 12:56:17 (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: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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](#)

Item	Date	User	Comment
2	Sep-22-2020 12:56:17 (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: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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](#)

Item	Date	User	Comment
3	Sep-22-2020 12:56:17 (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: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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](#)

Item	Date	User	Comment
4	Sep-22-2020 12:56:17 (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: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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](#)

Item	Date	User	Comment
5	Sep-22-2020 12:56:17 (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: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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](#)

Item	Date	User	Comment
6	Sep-22-2020 12:56:17 (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: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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](#)

Item	Date	User	Comment
7	Sep-22-2020 12:56:17 (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: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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](#)

Item	Date	User	Comment
8	Sep-22-2020 12:56:17 (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: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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](#)

Item	Date	User	Comment
9	Sep-22-2020 12:56:17 (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: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

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](#)

Item	Date	User	Comment
10	Sep-22-2020 12:56:17 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-22-2020 12:56:30 (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 - 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

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Sep-22-2020 12:56:30 (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 - 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

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2	Sep-22-2020 12:56:30 (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 - 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

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Sep-22-2020 12:56:30 (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 - 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

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4	Sep-22-2020 12:56:30 (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 - 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

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5	Sep-22-2020 12:56:30 (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: 11401002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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](#)

Item	Date	User	Comment
Form	Sep-22-2020 12:56:42 (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: 11401002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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](#)

Item	Date	User	Comment
1	Sep-22-2020 12:56:42 (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: 11401002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Sep-22-2020 12:56:42 (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 Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

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Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Sep-22-2020 12:56:42 (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

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Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Sep-22-2020 12:56:42 (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 Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

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Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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](#)

Item	Date	User	Comment
5	Sep-22-2020 12:56:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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](#)

Item	Date	User	Comment
6	Sep-22-2020 12:56:42 (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: 11401002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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](#)

Item	Date	User	Comment
7	Sep-22-2020 12:56:42 (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: 11401002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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](#)

Item	Date	User	Comment
8	Sep-22-2020 12:56:42 (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: 11401002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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](#)

Item	Date	User	Comment
9	Sep-22-2020 12:56:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

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](#)

Item	Date	User	Comment
10	Sep-22-2020 12:56:42 (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: 11401002

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

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](#)

Item	Date	User	Comment
Form	Sep-22-2020 12:56:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

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](#)

Item	Date	User	Comment
1	Sep-22-2020 12:56:59 (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: 11401002

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

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](#)

Item	Date	User	Comment
2	Sep-22-2020 12:56:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

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](#)

Item	Date	User	Comment
3	Sep-22-2020 12:56:59 (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: 11401002

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

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](#)

Item	Date	User	Comment
4	Sep-22-2020 12:56:59 (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: 11401002

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

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](#)

Item	Date	User	Comment
5	Sep-22-2020 12:56:59 (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: 11401002

Generated By: (b) (4)

Form: RADIATION TREATMENT - Comments

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](#)

Item	Date	User	Comment
6	Sep-22-2020 12:56:59 (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: 11401002

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

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](#)

Item	Date	User	Comment
Form	Sep-22-2020 12:57:10 (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: 11401002

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

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](#)

Item	Date	User	Comment
1	Sep-22-2020 12:57:10 (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: 11401002

Generated By: (b) (4)

Form: TRANSFUSIONS - Comments

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](#)

Item	Date	User	Comment
2	Sep-22-2020 12:57:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-15-2021 14:56:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	not applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - Comments

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-23-2021 12:52:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact

Form Version: 10-Dec-2020 02:25

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - Comments

Form Status: Data Complete

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-23-2021 12:52:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-19-2021 09:47:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject withdrawn from study prior to unblinding. Unblinding captured in paper source and not in EDC. <hr/> Not Applicable
Form	Feb-17-2021 14:19:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
Form	Feb-15-2021 14:57:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable
Form	Feb-11-2021 13:24:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
Form	Oct-26-2020 13:55:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Feb-19-2021 09:47:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject withdrawn from study prior to unblinding. Unblinding captured in paper source and not in EDC. <hr/> Not Applicable
1	Feb-17-2021 14:19:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
1	Feb-15-2021 14:57:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable
1	Feb-11-2021 13:24:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
1	Oct-26-2020 13:55:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Feb-19-2021 09:47:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject withdrawn from study prior to unblinding. Unblinding captured in paper source and not in EDC. <hr/> Not Applicable
2	Feb-17-2021 14:19:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
2	Feb-15-2021 14:57:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable
2	Feb-11-2021 13:24:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
2	Oct-26-2020 13:55:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-26-2020 13:56:01 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-26-2020 13:56:01 (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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Stephen Thomas	Approved	Mar-11-2021 11:26:51 (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 12:14:34 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Dec-15-2020 09:16:32 (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	Dec-09-2020 13:14:12 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Nov-17-2020 18:22:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30f7\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: 11401002

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	Nov-16-2020 12:56:33 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Nov-13-2020 12:29:00 (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	Nov-12-2020 14:54:14 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Oct-27-2020 06:00:16 (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.

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Oct-26-2020 13:55:50 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Stephen Thomas	Approved	Oct-13-2020 16:09:37 (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 10:54:02 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Stephen Thomas	Approved	Sep-24-2020 11:10:20 (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-24-2020 10:11:21 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Stephen Thomas	Approved	Sep-24-2020 08:29:10 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30f7\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: 11401002

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	Sep-24-2020 08:13:23 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Sep-23-2020 18:29:45 (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-23-2020 16:57:31 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Sep-23-2020 16:33:03 (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.

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Sep-22-2020 21:25:19 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Stephen Thomas	Approved	Sep-22-2020 15:05:23 (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-22-2020 12:24:58 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Stephen Thomas	Approved	Aug-26-2020 16:42:51 (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.

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jul-29-2020 16:57:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(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-29-2020 16:57:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - 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](#)

I. Consent Was:

Date	Location	User	Value	Reason
Jul-29-2020 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Jul/29/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: DEMOGRAPHY - 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. Subject ID

Date	Location	User	Value	Reason
Sep-22-2020 21:26:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	event added in AE CRF
Sep-22-2020 12:57:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Sep-22-2020 06:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020364540 '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
Jul-29-2020 16:57:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11401002	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jul-29-2020 16:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1956	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Jul-29-2020 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Jul-29-2020 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae30f7\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: 11401002

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Jul-29-2020 16:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(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 (For Pfizer only): IN01A00	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(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

I.a Criterion met?

Date	Location	User	Value	Reason
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090177e196ae30f7\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: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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1.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusion Number: Criteria Participants who are willing and able to comply with a on Design all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures Criteria YES on met ?: Criteria IN02A00 on ID: (For Pfizer use only) :	Initial Entry

090177e196ae30f7\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: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

I.b Inclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

I.b Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participants who are willing and able to comply with all scheduled visits, v accination plan, laboratory tests, lifes tyle considerations, and other study p rocedures	Initial Entry

I.b Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN02A00	Initial Entry

I.c

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Inclusi 3 on Nu mber: Criteria Healthy participants who ar on Des e determined by medical hi criptio story, physical examination, n: and clinical judgment of the investigator to be eligible f or inclusion in the study	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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>Criteria YES on met ?:</p> <p>Criteria IN03A00 on ID: (For Pfizer user use only) :</p>
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I.c Inclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	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 Publisher use only): IN04A00	
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090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:53

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Subject No: 11401002

Subject Initials: ---

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

I.d Inclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	Initial Entry

I.d Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Capable of giving personal signed in formed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

I.d Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: Criterion Description: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

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Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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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>Criteria NO on met?:</p> <p>Criteria EX01A00 on ID: (For Pfizer use only):</p>
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

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Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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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)	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
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2.b Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(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-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX02A00	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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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

2.c

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Exclusion Number:</p> <p>Criterion Description: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)</p> <p>Criterion met?: NO</p> <p>Criterion ID: (For Pfizer use only): EX03A00</p>	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

2.c Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: History of severe adverse reaction as 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-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 4 Criterion Description: Receipt of medications intended to prevent COVID-19 Criterion met?: NO Criterion ID: (For Pfizer use only): EX04A00	Initial Entry

090177e196ae30f7\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: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

2.d Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion Number: Criterion Description: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination Criterion met?: NO	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

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Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

			Criteria ID: EX08A00 For Pfizer use only):
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2.e Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(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-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 10	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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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

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(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-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX10A00	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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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

2.g

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Num 11 ber: Criterion Descr Women who are p reption: regnant or breastfe eding Criterion met?: NO Criterion ID: (EX11A00 For Pfizer use o nly):	Initial Entry

2.g Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Women who are pregnant or breastfe eding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
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090177e196ae30f7\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: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: EX12A00 (For Pfizer use only):	Initial Entry
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion 13	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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

(US & Canada)		(b) (4), (b) (6)	n Number: r: Criterion Subjects who receive immunosuppressive therapy on: , such as cytotoxic agents or systemic corticosteroids Criterion NO met?: Criterion EX13A01 ID: (For Pfizer use only):
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2.i Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(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-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
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090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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

Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 15 Criteria Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt through out the study Criteria met?: NO Criteria ID: EX14A01 (For Printer use only):	Initial Entry
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090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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

2.j Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(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-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX14A01	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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

[Back to Form](#)

2.k

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number: 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	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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

2.k Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participation in other studies involvi ng study intervention within 28 days prior to study entry and/or during stu dy participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion 17 Number: Criterion Previous participation in Descripti other studies involving s on: tudy intervention containi ning lipid nanoparticles Criterion NO met?:	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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 ID: (For Pfizer use only):	EX16A01
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2.1 Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Previous participation in other studies involving study interventions containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Exclusion Number:	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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>Criteria 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</p> <p>Criteria NO</p> <p>on met</p> <p>?:</p> <p>Criteria EX21A01</p> <p>on ID:</p> <p>(For Pfizer use only):</p>	
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090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:53

Site No: 1140

Subject No: 11401002

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

2.m Exclusion Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(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-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 16:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EX21A01	Initial Entry

090177e196ae30f7\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: 11401002

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jul-29-2020 16:58:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jul-29-2020 16:58:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30f7\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: 11401002

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](#)

I.a

Date	Location	User	Value	Reason
Jul-29-2020 16:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Ter Hypertension m: Start Date: UNK/UNK/1979 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 16:59:50 (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-29-2020 16:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 16:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1979	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 16:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
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090177e196ae30f7\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: 11401002

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-29-2020 17:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Hyperlipidemia Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry
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I.b Line/MH Number:

Date	Location	User	Value	Reason
Jul-29-2020 17:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Jul-29-2020 17:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyperlipidemia	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 17:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 17:00:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-24-2020 10:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 3 Medical History Term: Spontaneous Coronary artery dissection	Updated as per safety unit query

090177e196ae30f7\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: 11401002

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

			Start Date: Dec/7/2019 Ongoing: NO End Date: Dec/31/2019	
Jul-29-2020 17:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 3 mber: Medical Hist Spontaneous Coronar ory Term: y artery dissection Start Date: Dec/7/2019 Ongoing: YES	Initial Entry

090177e196ae30f7\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: 11401002

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-29-2020 17:01:02 (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-29-2020 17:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Spontaneous Coronary artery dissection	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 17:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/7/2019	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-24-2020 10:11:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO End Date: Dec/31/2019	Updated as per safety unit query
Jul-29-2020 17:01:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Jul-29-2020 17:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Seasonal Allergies Start Date: UNK/UNK/1974 Ongoing: YES	Initial Entry

090177e196ae30f7\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: 11401002

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
Jul-29-2020 17:01:34 (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
Jul-29-2020 17:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Seasonal Allergies	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 17:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1974	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 17:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Jul-29-2020 17:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Osteopenia Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae30f7\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: 11401002

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-29-2020 17:01:56 (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-29-2020 17:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteopenia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Jul-29-2020 17:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Jul-29-2020 17:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

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](#)

I. Date:

Date	Location	User	Value	Reason
Aug-18-2020 15:51:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Closed	Response satisfies query
Aug-18-2020 13:08:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Aug-14-2020 06:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	Re-Query: Thanks for confirming that assessment is not done. Please go to item level comment and select "not done" for reason incomplete section. This should be done for all missing data. Please update the data, else clarify.
Jul-29-2020 17:03:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-17-2020 11:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Aug-12-2020 04:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-11-2020 10:32:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Comment updated per query
Aug-10-2020 04:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Requery: Thanks for the response. Please indicate an item

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

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

				level comment for the vital signs that not collected as per CRF completion requirement section 4.7 to remove the blank flag.
Aug-07-2020 09:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Not collected in error. Will be collected at following visit.
Jul-31-2020 06:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 1: Opened	Vital signs date has complete, however, Weight, Height and units are incomplete. Could you please provide the data.

3. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 13:08:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-17-2020 11:23:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-18-2020 13:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7.a

Date	Location	User	Value	Reason
Jul-29-2020 17:03:05 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

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

(US & Canada)		(b) (4), (b) (6)	Temperature: 98.2 Temperature Unit: F Temperature Location: ORAL CAVITY
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7.a Record Identifier:

Date	Location	User	Value	Reason
Jul-29-2020 17:03:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jul-29-2020 17:03:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jul-29-2020 17:03:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Jul-29-2020 17:03:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Jul-29-2020 17:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jul-29-2020 17:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jul-29-2020 17:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jul-29-2020 17:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jul-29-2020 17:03:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jul-29-2020 17:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Jul-29-2020 17:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jul-29-2020 17:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jul-29-2020 17:03:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae30f7\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: 11401002

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Jul-29-2020 17:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jul-30-2020 13:58:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 220241	Initial Entry

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: 11401002

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
Jul-29-2020 17:03:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-29-2020 17:03:57 (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 13:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jul-30-2020 05:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-29-2020 17:03:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-29-2020 17:03:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jul/29/2020	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Aug-05-2020 13:42:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-05-2020 13:31:35 (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 13:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG56X	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 13:30:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPG56X	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-05-2020 13:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG56Y	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 13:30:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPG56Y	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-05-2020 13:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG56Z	Initial Entry

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 13:31:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPG56Z	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-05-2020 13:44:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BNB40C	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 13:44:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BNB40C	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-05-2020 13:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BNB40D	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 13:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BNB40D	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-05-2020 13:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BNB40F	Initial Entry

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 13:44:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BNB40F	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: 11401002

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
Jul-29-2020 17:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-29-2020 17:04:03 (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 11:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jul-30-2020 05:56:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-29-2020 17:04:03 (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.
Jul-29-2020 17:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jul/29/2020	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Aug-05-2020 13:42:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-05-2020 11:49:35 (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 11:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BNB408	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 11:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BNB408	Initial Entry

090177e196ae30f7\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: 11401002

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jul-29-2020 17:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jul-29-2020 17:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jul-29-2020 17:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jul-29-2020 17:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/29/2020 14:44	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jul-29-2020 17:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jul-29-2020 17:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae30f7\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: 11401002

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

7. Route:

Date	Location	User	Value	Reason
Jul-29-2020 17:04:35 (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-29-2020 17:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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-29-2020 17:04:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30f7\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: 11401002

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

[Back to Form](#)

I. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-10-2020 02:40:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-07-2020 09:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Aug-07-2020 09:35:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E -DIARY COLLECTED FOR THIS SUBJECT	Initial Entry
Jul-31-2020 06:14:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	REACTOGENICITY DIARY is incomplete. Could you please provide the data

090177e196ae30f7\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: 11401002

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Aug-17-2020 13:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> FE VE R <u>Were fever or systemic sympt</u> <u>oms present on the last day th</u> <u>e Subject Diary was complete</u> <u>d?:</u> NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> 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-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> FAT IG UE	Initial Entry

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> HEADACHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

2.d

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: CH ILL S Were fever or systemic sympt oms present on the last day t he Subject Diary was comple ted?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (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-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (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 sym ptoms present on the last da y the Subject Diary was co mpleted?: NO	Initial Entry

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (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-17-2020 13:35:42 (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-17-2020 13:35:42 (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 sym NO ptoms present on the last da y the Subject Diary was com pleted?:	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (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-17-2020 13:35:42 (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
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090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE ED MUSC LE PAIN Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?: NO	Initial Entry
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2.g Symptom:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEW OR WORSE NED MUSCLE P AIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (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-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Symptom:: NEW OR WORSE NED JOIN T PAIN Were fever or systemic symptoms present on t he last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

2.h Symptom:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (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-17-2020 13:35:42 (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-17-2020 13:35:42 (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-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Aug-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (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-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction NO s present on the last day the Subject Diary was complete d?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (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-17-2020 13:35:42 (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-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN A T INJEC TION SI	Initial Entry

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Aug-17-2020 13:35:42 (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-17-2020 13:35:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401002

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-17-2020 13:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-17-2020 13:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.4 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:06 (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-17-2020 13:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 98.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-17-2020 13:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401002

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

Aug-17-2020 13:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 17-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

3. Collection Date:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-17-2020 13:37:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin in Beta_PX113 Result:: Not Done::	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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-17-2020 13:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 13:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-18-2020 11:10:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-18-2020 11:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Aug-18-2020 11:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-18-2020 02:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	DM Query: 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-17-2020 13:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Aug-17-2020 13:37:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Aug-18-2020 11:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPYZG4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 11:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPYZG4	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-18-2020 11:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error (DELETED)
Aug-18-2020 11:10:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID:	Transcription Error
Aug-18-2020 11:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPYZG5	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sample ID

Date	Location	User	Value	Reason
Aug-18-2020 11:11:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Transcription Error (DELETED)
Aug-18-2020 11:10:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Transcription Error
Aug-18-2020 11:10:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPYZG5	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401002

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-17-2020 13:37:51 (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-17-2020 13:37:51 (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-17-2020 13:37:51 (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-17-2020 13:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/17/2020 09:51	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

7. Route:

Date	Location	User	Value	Reason
Aug-17-2020 13:37:51 (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-17-2020 13:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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-17-2020 13:37:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 15-Sep-2020 21:55**Site No:** 1140**Subject No:** 11401002**Generated By:** (b) (4)**Form:** DISPOSITION - 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[Back to Form](#)***I. Date of Completion/Discontinuation/Death :***

Date	Location	User	Value	Reason
Dec-11-2020 05:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-09-2020 13:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-09-2020 13:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sep/17/2020	New Information
Nov-25-2020 11:19:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	DM: Please update the date to the Withdrawal of Consent date (17SEP2020).
Nov-13-2020 16:17:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 11:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-13-2020 11:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/28/2020	Changed Information
Nov-13-2020 02:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	DM : Thanks for the response. However, Date of Completion/Discontinuation /Death (17/Sep/2020) is still not between AE start date 28AUG2020 and end date 28AUGP2020 which causing withdrawal of the study vaccine. Please review and update. Else,clarify.
Nov-12-2020 14:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 15:55:04	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM2: The End of

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, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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)		Treatment form is not locked.
Nov-11-2020 09:21:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Please unlock the crf in order to update the data
Nov-10-2020 22:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	The discontinuation date of 17SEP2020 should be relative to the AE causing the the withdrawal of the study vaccine, AE start 28AUG2020 and end 28AUG2020 (date should not be after the AE ended). Please adjust Discontinuation date.
Sep-23-2020 16:57:31 (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-23-2020 16:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-16-2020 18:24:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Nov-16-2020 12:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Answered	This is the date subject had V2. Therefore, treatment end date will remain as is.
Nov-13-2020 15:43:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 6: Opened	DMW5377732;Status is "WITHDRAWAL BY SUBJECT", but date is different than date on Withdrawal

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

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, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

				of Consent form. Please review and update as appropriate.
Nov-12-2020 14:55:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Nov-12-2020 14:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	Response to "Status" is WITHDRAWAL BY SUBJECT but "Specify Status" is missing.
Nov-12-2020 14:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: WITHDRAWAL BY SUBJECT	Changed Information
Oct-13-2020 14:33:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 4: Closed	Response satisfies query
Oct-13-2020 13:06:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Answered	This has been addressed accordingly.
Oct-06-2020 15:30:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 4: Opened	CLINQUERY: Please review the Adverse Events under the Log tab and select which led to treatment discontinuation. At least one AE needs to have the 'Latest Action Taken with Study Treatment' field completed as DRUG WITHDRAWN to match to this entry
Sep-24-2020	ACV0PFEINFP6000	Saumitra Dubey	Query 2:	Response satisfies

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

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, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

10:36:51 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)	Closed	query
Sep-24-2020 08:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Sep-24-2020 08:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Sep-24-2020 08:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Sep-24-2020 08:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ADVERSE EVENT	Changed Information
Sep-23-2020 18:09:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 2: Opened	Please consider if this status AND FUP status should be ADVERSE EVENT as reported by previous query and if so, remove specify as well.
Sep-23-2020 18:07:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Sep-23-2020 18:04:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Opened	Please consider if this status AND FUP status should be ADVERSE EVENT as reported by previous query.

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

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, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Sep-23-2020 16:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: WITHDR AWAL B Y SUBJE CT	Initial Entry
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4. Specify Status:

Date	Location	User	Value	Reason
Nov-12-2020 14:55:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Subject no longer wanted to participate after experiencing a spontaneous coronary artery dissection	Initial Entry
Sep-24-2020 08:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Changed Information
Sep-23-2020 16:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Withdrawal of consent due to SAE	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - 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](#)

I. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-16-2020 18:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 13:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 17:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for your response. If subject withdrew consent after AE resolved, reason for withdrawal should not be AE and the AE should not have Yes for causing study discontinuation. Please update forms as applicable.
Nov-11-2020 12:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	17Sep2020 is the date that subject contacted site to vocalize her discontinuation of the study. Date should remain as is for consistency, as the conversation on 17Sep2020 is documented in source in subjects paper chart.
Nov-10-2020 22:46:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	The discontinuation date of 17SEP2020 should be relative to the AE causing the the withdrawal of the study vaccine, AE start 28AUG2020 and end 28AUG2020 (date should not be

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - 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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

				after the AE ended). Please adjust Discontinuation date.
Sep-23-2020 16:58:29 (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-23-2020 16:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-12-2020 14:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-12-2020 14:56:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is WITHDRAWAL BY SUBJECT but "Specify Status" is missing.
Nov-12-2020 14:56:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate after experiencing a spontaneous coronary artery dissection
Sep-24-2020 08:14:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-24-2020 08:14:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Sep-24-2020 08:14:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ADVERSE EVENT	Changed Information
Sep-23-2020 16:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: WITHDRAWAL BY SUBJECT	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - 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. Specify Status:

Date	Location	User	Value	Reason
Nov-12-2020 14:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Subject no longer wanted to participate after experiencing a spontaneous coronary artery dissection	Initial Entry
Sep-24-2020 08:14:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Changed Information
Sep-23-2020 16:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Withdrawal of consent due to SAE	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401002

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 ***

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-23-2020 10:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Deleted	AE same as the eDiary entry.
Sep-22-2020 12:24:58 (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: 11401002

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 ***

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-23-2020 10:40:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Deleted	AE same as the eDiary entry
Sep-22-2020 12:26:06 (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: 11401002

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-22-2020 12:30:03 (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: 11401002

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

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-16-2020 12:56:33 (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: 11401002

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-22-2020 12:24:58 (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-22-2020 12:24:58 (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
Sep-23-2020 15:30:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Sep-23-2020 10:39:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	AE same as the eDiary entry.
Sep-23-2020 06:03:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	eDiary: AE Injection site pain reported with start date 30-Jul-2020 and End Date 01-Aug-2020 seems to be same as e-Diary occurrence Injection site pain reported on 30-Jul-2020. Please reconcile or confirm in

090177e196ae30f7\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: 11401002

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 ***

				the query response as appropriate. "[naikp09 SDQ=11067]"
Sep-22-2020 12:24:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Pain at Injecti on site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-22-2020 12:24:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jul/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-22-2020 12:24:58 (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 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-22-2020 12:24:58 (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
Sep-22-2020 12:24:58	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae30f7\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: 11401002

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 ***

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

(b) (4), (b) (6) 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-22-2020 12:24:58 (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
Sep-22-2020 12:24:58 (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
Sep-22-2020 12:24:58 (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
Sep-22-2020 12:24:58 (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
Sep-22-2020 12:24:58 (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
Sep-22-2020 12:24:58 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

090177e196ae30f7\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: 11401002

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

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(US & Canada)

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

Date	Location	User	Value	Reason
Sep-22-2020 12:24:58 (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: 11401002

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-22-2020 12:26:06 (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-22-2020 12:26:06 (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
Sep-23-2020 15:30:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Sep-23-2020 10:40:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	AE same as the eDiary entry
Sep-23-2020 06:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	eDiary: AE Diarrhea reported with start date 31-Jul-2020 and End Date 31-Jul-2020 seems to be same as e-Diary occurrence Diarrhea reported on 31-Jul-2020. Please reconcile

090177e196ae30f7\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: 11401002

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 ***

				or confirm in the query response as appropriate. "[naikp09 SDQ=11066]"
Sep-22-2020 12:26:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Diarrhea	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-22-2020 12:26:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jul/31/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-22-2020 12:26:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO End Date Time: Jul/31/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-22-2020 12:26:06 (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
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090177e196ae30f7\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: 11401002

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 ***

Sep-22-2020 12:26:06 (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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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-22-2020 12:26:06 (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-22-2020 12:26:06 (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
Sep-22-2020 12:26:06 (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-22-2020 12:26:06 (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
Sep-22-2020 12:26:06 (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
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090177e196ae30f7\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: 11401002

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 ***

Sep-22-2020 12:26:06 (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
Sep-22-2020 12:26:06 (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: 11401002

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-22-2020 12:30:03 (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
Sep-22-2020 12:30:03 (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
Oct-24-2020 19:33:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	THANK YOU.
Oct-22-2020 16:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	SAE FOLLOW/UP REPORT UPDATED
Oct-22-2020 13:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	COVID testing has not been recorded in the SAE submitted to safety. If test performed = YES, please provide FU form with results. If NOT test performed or available, please submit FU form as well so it is reflected

090177e196ae30f7\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: 11401002

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

				in the narrative.
Sep-24-2020 10:21:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Spontaneous coronary arte ry dissection	Changed Information
Sep-23-2020 15:44:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Clos ed	Response satisfies query
Sep-23-2020 15:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Updated term to add worsening of condition
Sep-23-2020 15:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Worsening of Spontaneous coronary arte ry dissection	Updated term to add worsening of condition
Sep-23-2020 04:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Ope ned	The AE Spontaneous coronary artery dissection was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. "[naikp09 SDQ=11054]"

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Sep-22-2020 12:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Spontaneous coronary arte ry dissection	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Nov-16-2020 13:05:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Nov-16-2020 12:59:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-12-2020 22:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per case narrative, "The subject may have suffered some myocardial ischemia." If this is an additional AE, please revise/update AE log accordingly. Thank you.
Sep-22-2020 12:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-22-2020 12:30:03 (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 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-22-2020 12:30:03 (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?

090177e196ae30f7\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: 11401002

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

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 21:25:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 12:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Spontaneous coronary artery dissection : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-22-2020 12:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES	Initial Entry

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

			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-22-2020 12:30:03 (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
Sep-22-2020 12:30:03 (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> History of coronary artery dissection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-13-2020 15:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_AE001_32
Nov-13-2020 11:28:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-13-2020 11:28:02 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Changed Information

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
Nov-13-2020 06:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: O pened	DMW5372244;The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Disposition- Treatment Form Status is not DEATH OR ADVERSE EVENT. Please review and update as appropriate.
Oct-13-2020 10:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entr y: DRUG WI THDRAW N	New Information
Sep-22-2020 12:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entr y: NOT APPL ICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-22-2020 12:30:03 (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
Sep-22-2020 12:30:03 (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
Sep-22-2020 12:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Sep-22-2020 12:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Sep-22-2020 12:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Spontaneous coronary artery dissection : Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-22-2020 12:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 13:26:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	New Information
Sep-23-2020 18:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Deleted	moved the query to the EOT form as this data is confirmed as correct below.
Sep-23-2020 16:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Sep-23-2020 15:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Reissued:Opened	Please enter EOT form, FUP form, withdrawal of consent forms.

090177e196ae30f7\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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Sep-23-2020 15:41:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Confirmed that response "Yes" is correct as subject withdrew consent from study due to this adverse event.
Sep-23-2020 06:29:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Sep-22-2020 12:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.
Sep-22-2020 12:30:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-22-2020 21:25:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (6)	Data Entry: 2020363609	Initial Entry

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:33 (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
Nov-17-2020 15:42:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Nov-17-2020 13:33:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed as per monitor request from query
Nov-17-2020 13:33:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Myocardial Ischemia	Changed as per monitor request from query
Nov-16-2020 16:31:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term MYOCARDIAL ISCHEMIA- RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION. Split the term into

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

				MYOCARDIAL ISCHEMIA and SPONTANEOUS CORONARY ARTERY DISSECTION and submit separately. Thank you.
Nov-16-2020 12:57:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Myocardial Ischemia- Related to spontaneous coronary artery dissection	updated
Nov-16-2020 12:56:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Myocardial Ischemia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-16-2020 12:56:33 (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 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:33 (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.

090177e196ae30f7\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

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

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
Nov-16-2020 12:56:33 (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
Nov-16-2020 12:56:33 (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
Nov-16-2020 12:58:24 (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> Suffered some myocardial isch emia at the time of dissection	updated per SD
Nov-16-2020 12:56:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 12:56:33 (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
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090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

Nov-16-2020 12:56:33 (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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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-16-2020 12:56:33 (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
Nov-16-2020 12:56:33 (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
Nov-16-2020 12:56:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-22-2020 12:56:17 (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
Sep-22-2020 12:56:17 (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
Sep-22-2020 12:56:17 (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
Sep-22-2020 12:56:17 (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
Sep-22-2020 12:56:17 (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
Sep-22-2020 12:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401002

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

7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-22-2020 12:56:17 (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
Sep-22-2020 12:56:17 (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
Sep-22-2020 12:56:17 (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
Sep-22-2020 12:56:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f7\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: 11401002

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
Sep-22-2020 12:56:30 (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-22-2020 12:56:30 (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-22-2020 12:56:30 (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-22-2020 12:56:30 (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
Sep-22-2020 12:56:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f7\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, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

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
Sep-22-2020 12:56:42 (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-22-2020 12:56:42 (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-22-2020 12:56:42 (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-22-2020 12:56:42 (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-22-2020 12:56:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
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090177e196ae30f7\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, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Sep-22-2020 12:56:42 (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. Dose Frequency:

Date	Location	User	Value	Reason
Sep-22-2020 12:56:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Sep-22-2020 12:56:42 (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-22-2020 12:56:42 (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-22-2020 12:56:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: RADIATION TREATMENT - 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. Category:

Date	Location	User	Value	Reason
Sep-22-2020 12:56:59 (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
Sep-22-2020 12:56:59 (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
Sep-22-2020 12:56:59 (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-22-2020 12:56:59 (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-22-2020 12:56:59 (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
Sep-22-2020 12:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f7\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: 11401002

Generated By: (b) (4)

Form: TRANSFUSIONS - 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. Transfusion Type:

Date	Location	User	Value	Reason
Sep-22-2020 12:57:10 (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
Sep-22-2020 12:57:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f7\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, Verified**Site No:** 1140**Site Name:** (1140) SUNY Upstate Medical University**Subject No:** 11401002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Feb-24-2021 07:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Del eted	Query is invalid or does not apply
Feb-23-2021 17:09:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 5: Clo sed	Response satisfies query
Feb-23-2021 12:53:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 5: Ans wered	updated per query request
Feb-23-2021 12:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Can didate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-22-2021 02:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Op ened	CLINQUERY: Confirmed subject off study prior to this contact. Since date cannot be removed, please mark DOV as 'erroneous' via the radio button in next field and add form level comment to next page as 'Not Applicable' to close this folder
Feb-19-2021	ACV0PFEINFP6000	Hayley Wyper	Query	CLINQUERY: Confirmed

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, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

17:32:01 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)	5: Can didate	subject off study prior to this contact. Since date cannot be removed, please mark DOV as 'erroneous' via the radio button in next field and add form level comment to next page as 'Not Applicable' to close this folder
Feb-19-2021 17:30:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 4: Del eted	reviewed
Feb-19-2021 12:13:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 4: Can didate	CLINQUERY: Treatment Unblind pages updated but not the revax contact pages. Please also review removal of this data since dated post end of study (Disp FUP date) and subject not intending to re-join trial
Feb-16-2021 09:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Clo sed	Close Auto Query
Feb-16-2021 05:51:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Op ened	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-16-2021 01:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001		Form: DATE OF VISIT - eCRF Audit Trail History		
Visit: Potential ReVax Initial Contact - Unscheduled		Form Status: Data Complete, Verified		
Form Version: 22-Apr-2020 21:02		Site Name: (1140) SUNY Upstate Medical University		
Site No: 1140		Subject Initials: ---		
Subject No: 11401002		Generated Time (GMT): 29-Mar-2021 11:44		
Generated By: (b) (4)				
Feb-15-2021 14:56:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Ans wered	erroneous visit is marked
Feb-15-2021 14:55:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Can didate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-12-2021 04:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Clo sed	Query present for same issue
Feb-12-2021 00:19:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Rei ssued: Opene d	DM: No Data expected to enter post FUP date. Please verify dates, details and update accordingly. Thank you.
Feb-11-2021 13:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Ans wered	SUBJECT WAS CONTACTED TO CONVEY HER STRATIFICATION
Feb-11-2021 13:26:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Ans wered	SUBJECT WAS DISCONTINUED FROM THE STUDY. WE UNBLINDED HER TO CONVEY HER STRATIFICATION
Feb-10-2021 22:35:06 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Op ened	DMW7226166;'Date of Visit' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please

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, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				clarify or correct.
Feb-10-2021 13:37:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry : Jan/11 /2021	Transcription Error
Feb-10-2021 12:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Op ened	Date of Visit is after the Date of Completion/Discontinuation /Death on the Follow-Up Disposition form. Please review and update as appropriate.
Feb-10-2021 12:14:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry : Jan/5/ 2021	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Feb-23-2021 12:52:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry
Feb-16-2021 09:14:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Changed Information
Feb-15-2021 14:55:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-23-2021 17:09:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Feb-23-2021 12:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	updated per query request
Feb-23-2021 12:52:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-22-2021 07:11:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Reissued:Opened	CLINQUERY: To close down pages in this folder, please add a form level comment of 'Not Applicable' to this page and mark the DOV page as 'erroneous' (date cannot be removed once entered)
Feb-19-2021 14:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Feb-19-2021 14:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-19-2021 14:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Transcription Error
Feb-19-2021 12:12:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Reissued:Opened	CLINQUERY: Treatment Unblind pages updated but not the revax contact pages. Please also review removal of this data since dated post end of study (Disp FUP date)

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

Feb-19-2021 09:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	Data removed as per query request.
Feb-19-2021 09:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-17-2021 14:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Feb-17-2021 01:48:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-16-2021 16:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Reissued:Opened	CLINQUERY: If subject has not re-joined study, please only capture treatment unblind in source. No data should appear in the CRF after end of study date (Disp FUP)
Feb-16-2021 09:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1140**Subject No:** 11401002**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History**Form Status:** Data Complete**Site Name:** (1140) SUNY Upstate Medical University**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44

Feb-16-2021 09:15:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Initial Entry
Feb-16-2021 09:15:16 (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 V accination 1/2	Initial Entry
Feb-15-2021 15:24:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Reissued:Opened	CLINQUERY: Please add a form level comment of Not Done to close this page.
Feb-15-2021 14:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-15-2021 14:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Changed Information
Feb-11-2021 18:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Reissued:Opened	CLINQUERY: If subject has not re-joined study, please only capture treatment unblind in source. No data should appear in the CRF after end of study date (Disp FUP)
Feb-11-2021 13:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-11-2021 13:25:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Participant is NOT willing to retur n for Vaccination 3 OR otherwise n ot eligible	Transcription Error
Feb-11-2021 13:24:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

Feb-11-2021 12:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: The revax contact reports subject has re-joined trial in order to proceed with re-vaccination (subject had previously withdrawn). Please review and confirm if this is correct.
Feb-11-2021 01:56:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-10-2021 12:16:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-10-2021 12:16:41 (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 V accination 1/2	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

I. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-19-2021 16:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Clo sed	Auto closed by Validation Check: VC_DS001_15_AN
Feb-19-2021 09:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry : Not A pplica ble	Initial Entry
Feb-19-2021 09:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ans wered	Data changed per query request.
Feb-19-2021 09:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry :	Data changed per query request.
Feb-17-2021 22:48:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Op ened	DMW7288814; 'Date Treatment Unblinded' is after 'Date of Completion/Discontinuation '/Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Feb-17-2021 14:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry : Jan/11 /2021	Initial Entry
Feb-17-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Data	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

14:19:11 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	<u>Entry</u> :	
Feb-15-2021 21:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Clo sed	Auto closed by Validation Check: VC_DS001_15_AN
Feb-15-2021 15:23:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Clo sed	Response satisfies query
Feb-15-2021 14:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry</u> : Not A pplica ble	Initial Entry
Feb-15-2021 14:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Changed Information
Feb-15-2021 14:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Changed Information
Feb-15-2021 14:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry</u> :	Changed Information
Feb-11-2021 23:17:22 (UTC-05:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Op ened	DMW7238548;'Date Treatment Unblinded' is after 'Date of

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Feb-11-2021 18:31:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: If subject has not re-joined study, please only capture treatment unblind in source. No data should appear in the CRF after end of study date (Disp FUP)
Feb-11-2021 13:24:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry : Jan/11 /2021	Initial Entry
Feb-11-2021 13:24:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry :	Initial Entry
Oct-26-2020 13:55:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry : Not Applicable	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-19-2021 09:47:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-19-2021 09:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Data changed per query request.
Feb-17-2021 14:20:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: OTHER If other, specify: Subject no longer participating in	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

			trial, but was contacted to advise of receipt of BNT162b2	
Feb-17-2021 14:19:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Feb-15-2021 14:57:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Feb-15-2021 14:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Changed Information
Feb-11-2021 13:24:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDI TIONAL VACCINATION	Initial Entry
Feb-11-2021 13:24:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-26-2020 13:55:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

I. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Sep-23-2020 15:35:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sep/17/2020	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

I. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Oct-26-2020 13:56:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1140**Subject No:** 11401002**Generated By:** (b) (4)**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1140) SUNY Upstate Medical University**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**I. Subject Status**

Date	Location	User	Value	Reason
Nov-12-2020 14:56:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Subject no longer wanted to participate after experiencing a spontaneous coronary artery dissection
Nov-12-2020 14:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Changed Information
Sep-24-2020 08:14:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Changed Information
Sep-24-2020 08:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Changed Information
Sep-23-2020 16:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Sep-23-2020 16:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Jul-29-2020 17:03:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jul-29-2020 16:58:54 (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
Jan-06-2021 00:35:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021 15:30:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Subject edairy has been deactivated.

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: 11401002

Subject Initials: ---

Generated By: (b) (4)

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

Jan-04-2021 16:14:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (b) (4)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 28DEC2020. But there is no COVID Illness visit reported in the database. Please clarify.
Dec-09-2020 13:14:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/17/2020	New Information
Nov-13-2020 11:30:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/17/2020	Changed Information
Nov-12-2020 14:56:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/17/2020	Subject no longer wanted to participate after experiencing a spontaneous coronary artery dissection
Nov-12-2020 14:54:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/17/2020	Changed Information
Sep-24-2020 08:14:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/17/2020	Changed Information
Sep-24-2020 08:13:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/17/2020	Changed Information
Sep-23-2020 16:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/17/2020	Initial Entry
Sep-23-2020 16:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/17/2020	Initial Entry
Jul-29-2020 17:03:38 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/29/2020	Initial Entry

090177e196ae30f7\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

Time (US & Canada)				
Jul-29-2020 16:58:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/29/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401002

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Aug-26-2020 14:33:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

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