

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1140

**Subject No:** 11401035

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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 Aug/4/2020
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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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11401035]
2.	Birth Date:	(b) (6)/1958
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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/4/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1140

**Subject No:** 11401035

**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

**Form Comments**

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable
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**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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	Aug/4/2020
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:** 11401035

**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:	Jan/UNK/2012
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[High cholesterol]
	Start Date:	Jan/UNK/2012
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GERD]
	Start Date:	Aug/UNK/2019
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Peritonsillar abscess]
	Start Date:	UNK/UNK/1984
	Ongoing:	NO End Date: UNK/UNK/1984

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

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:	[Deviated septum repair]
	Start Date:	UNK/UNK/2009
	Ongoing:	NO End Date: UNK/UNK/2009
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fever of Unknown Origin]
	Start Date:	UNK/UNK/2012
	Ongoing:	NO End Date: UNK/UNK/2012
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[(+ purified protein derivative)]
	Start Date:	UNK/UNK/1984
	Ongoing:	NO End Date: UNK/UNK/1984
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Idiopathic Urticaria]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/4/2020
2.	Weight:	[202.0]
3.	Unit:	LB
4.	Height:	[69.6]
5.	Unit:	in
6.	Body Mass Index:	[29.3]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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 :	Aug/4/2020
2.	Randomization Number:	[222344]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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: Aug/4/2020
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	[BPG596]
5.b	Sample ID	[BPG597]
5.c	Sample ID	[BNB44R]
5.d	Sample ID	[BNB44S]
5.e	Sample ID	[BNB44T]

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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/4/2020
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	[BNB44N]
-----	-----------	----------

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**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/4/2020 15:01
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

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1140

**Subject No:** 11401035

**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:** 11401035

**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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Not Done _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Done _____	<a href="#">Comments</a>

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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

[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?	Not Done _____	<a href="#">Comments</a>
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2 f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**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?	Not Done _____	<a href="#">Comments</a>
3.	Injection Site Location:	Not Done _____	<a href="#">Comments</a>
4.	Injection Site Body Side:	Not Done _____	<a href="#">Comments</a>
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Done _____	<a href="#">Comments</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1140

**Subject No:** 11401035

**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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Not Done _____ //	<a href="#">Comments</a>
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**Vital Signs Details**

2.a	Record Identifier:	Not Done _____ 1	
	Temperature:	Not Done _____ [ ]	<a href="#">Comments</a>
	Unit:	Not Done _____	<a href="#">Comments</a>
	Temperature Location:	Not Done _____	<a href="#">Comments</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	Not Done _____	<a href="#">Comments</a>
2.	Sample Type	Not Done _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Done _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Done _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ [ ]
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090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401035

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

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

Vaccination			
1.	Was there a temporary delay of vaccination?	Not Done _____	<a href="#">Comments</a>
2.	Treatment Name	Not Done _____ [ ]	<a href="#">Comments</a>
3.	Formulation:	Not Done _____	<a href="#">Comments</a>
4.	Dose Date Time:	Not Done _____ //	<a href="#">Comments</a>
5.	Anatomical Location:	Not Done _____	<a href="#">Comments</a>
6.	Body Side:	Not Done _____	<a href="#">Comments</a>
7.	Route:	Not Done _____	<a href="#">Comments</a>
8.	Actual Dose:	Not Done _____ [ ]	<a href="#">Comments</a>
9.	Unit:	Not Done _____	<a href="#">Comments</a>
10.	Timeframe Subject Was Observed	Not Done _____	<a href="#">Comments</a>
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done _____	<a href="#">Comments</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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:** 11401035

**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?	

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**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:** 11401035

**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:** 11401035

**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:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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:** 11401035

**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:** 11401035

**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:** 11401035

**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:** 11401035

**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:** 11401035

**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:** 11401035

**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:** 11401035

**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:** 11401035

**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:** 11401035

**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:** 11401035

**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\_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:** 11401035

**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 1 - Unscheduled Visit on  
Sep/22/2020

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/22/2020

**Form:** UNPLANNED VISIT

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/22/2020

**Form:** CONTACT OUTCOME - UNPLANNED

**Form Version:** 22-Apr-2020 21:04  
**Site No:** 1140

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

**Subject No:** 11401035

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

**Generated By:** (b) (4)

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Sep/22/2020  Contact Outcome: VISIT ARRANGED
3.	Comments:	[Subject attended clinic visit for safety check after subject treatment was discontinued prior to receiving second injection. Subject will continue to complete study visits going forward.]



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/22/2020

**Form:** VITAL SIGNS - TEMP

**Form Version:** 15-Sep-2020 21:54

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/22/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Sep/22/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

**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](#)

**Unplanned Assessment Of Local Reaction**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Injection Site Location	Not Applicable _____	<a href="#">Comments</a>
3.	Injection Site Body Side:	Not Applicable _____	<a href="#">Comments</a>

**Reaction**

4.a	Reaction:	REDNESS	
	Reaction Present:	Not Applicable _____	<a href="#">Comments</a>
4.b	Reaction:	SWELLING	
	Reaction Present:	Not Applicable _____	<a href="#">Comments</a>

**Symptom**

5.a	Symptom:	PAIN AT INJECTION SITE	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.b	Symptom:	FATIGUE/TIREDNESS	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.c	Symptom:	HEADACHE	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.d	Symptom:	VOMITING	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Sep/22/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

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

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

**Subject Initials:** ---

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

5.e	Symptom:	DIARRHEA	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.h	Symptom:	CHILLS	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 22-Apr-2020 21:05

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** DISPOSITION - 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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Sep/22/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1140

**Subject No:** 11401035

**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/22/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401035

**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:	
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**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:** 11401035

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	urticaria	Aug/13/2020 UNK:UNK	NO End Date Time: Aug/13/2020 UNK:UNK	<a href="#">Repeating Pages</a>



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401035

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:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[urticaria]
4.	Start Date Time:	Aug/13/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/13/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [idiopathic urticaria (pre-existing on med hx)]
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

**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:** 11401035

**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	<a href="#">Repeating Pages</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1140

**Subject No:** 11401035

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

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**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	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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 _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
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 _____ [ ]	<a href="#">Comments</a>
5.	Date:	Not Applicable _____ //	<a href="#">Comments</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1. DELETED	1	CORTICOSTEROIDS	NO	Prednisone	60	<a href="#">Repeating Pages</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

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](#)

**Concomitant Medications**

1.	What is the medication identifier?	[4]
2.	Category:	CORTICOSTEROIDS
3.	Concomitant Medications Pre-specified:	NO
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).	[Prednisone]
5.	Dose:	[60]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	Aug/13/2020
10.	Ongoing?	NO End Date: Aug/23/2020

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**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	<a href="#">Repeating Pages</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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 _____	<a href="#">Comments</a>
2.	What is the treatment Identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Treatment:	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**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	<a href="#">Repeating Pages</a>

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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 _____	<a href="#">Comments</a>
2.	Date of Transfusion:	Not Applicable _____ //	<a href="#">Comments</a>

**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:** 11401035

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401035

**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?	

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**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:** 11401035

**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:** 11401035

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**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:** 11401035

**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:** 11401035

**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:** Not Started

**Site No:** 1140

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

**Subject No:** 11401035

**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:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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 _____ //	<a href="#">Comments</a>
2.	Primary Reason for Unblinding:	Not Applicable _____	<a href="#">Comments</a>



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Withdrawal Of Consent**

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

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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/22/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**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:** 11401035

**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 15:40:14 (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:** 30-Jul-2020 21:29

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - 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-07-2020 08:26:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - 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-26-2020 11:39:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - 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	Aug-26-2020 11:39:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - 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-26-2020 11:39:09 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.a	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.b	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.c	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.d	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.e	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.f	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.g	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2.h	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.a	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.b	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - Comments

**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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.c	Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - 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-26-2020 11:40:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - 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	Aug-26-2020 11:40:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - 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.a	Aug-26-2020 11:40:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - 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.a	Aug-26-2020 11:40:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - 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.a	Aug-26-2020 11:40:13 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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-26-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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	Aug-26-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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-26-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

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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

[Back to Form](#)

Item	Date	User	Comment
3	Aug-26-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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-26-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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	Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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	Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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	Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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	Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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	Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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	Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** VACCINATION - 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
11	Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject discontinued from study by choice of provider as he was recently prescribed a very high dose of Prednisone taper (60mg) and is therefore not eligible to receive the second vaccine dose. <hr/> Not Done

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Sep/22/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable



**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1140

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

**Subject No:** 11401035

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**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4.a	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1140

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

**Subject No:** 11401035

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**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
4.b	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.a	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.b	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1140

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

**Subject No:** 11401035

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**Generated By:** (b) (4)

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[Back to Form](#)

Item	Date	User	Comment
5.c	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

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**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.d	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable



**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.e	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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

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**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.f	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

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**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.g	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

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**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

**Form Version:** 15-Sep-2020 21:51

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
5.h	Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject did not receive second vaccination dose so vaccination diary not completed. <hr/> Not Applicable

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**Form Version:** 17-Jul-2020 21:54

**Site No:** 1140

**Subject No:** 11401035

**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	Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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**Site No:** 1140

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
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**Header Text:** c4591001

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
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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	Oct-08-2020 15:46:41 (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 Name:** (1140) SUNY Upstate Medical University

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

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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
5	Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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**Site No:** 1140

**Subject No:** 11401035

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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

[Back to Form](#)

Item	Date	User	Comment
6	Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

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**Form Version:** 17-Jul-2020 21:54

**Site No:** 1140

**Subject No:** 11401035

**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	Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

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**Form Version:** 17-Jul-2020 21:54

**Site No:** 1140

**Subject No:** 11401035

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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

[Back to Form](#)

Item	Date	User	Comment
8	Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

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**Form Version:** 17-Jul-2020 21:54

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

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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

[Back to Form](#)

Item	Date	User	Comment
9	Oct-08-2020 15:46:41 (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:** 17-Jul-2020 21:54

**Site No:** 1140

**Subject No:** 11401035

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**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	Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-08-2020 15:46:57 (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

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**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-08-2020 15:46:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - Comments

**Form Version:** 22-Apr-2020 21:03

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
2	Oct-08-2020 15:46:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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VACCINATIONS - Comments

**Form Version:** 22-Apr-2020 21:03

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

**Subject No:** 11401035

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**Generated By:** (b) (4)

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

[Back to Form](#)

Item	Date	User	Comment
3	Oct-08-2020 15:46:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

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VACCINATIONS - Comments

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[Back to Form](#)

Item	Date	User	Comment
4	Oct-08-2020 15:46:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

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VACCINATIONS - Comments

**Form Version:** 22-Apr-2020 21:03

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**Subject No:** 11401035

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Oct-08-2020 15:46:57 (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:** 11401035

**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	Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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**Site No:** 1140

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**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	Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

[Back to Form](#)

Item	Date	User	Comment
2	Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

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**Form:** RADIATION TREATMENT - Comments

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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[Back to Form](#)

Item	Date	User	Comment
5	Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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**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	Oct-08-2020 15:47:12 (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:** 11401035

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - 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
Form	Oct-08-2020 15:47:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-08-2020 15:47:27 (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 Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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[Back to Form](#)

Item	Date	User	Comment
2	Oct-08-2020 15:47:27 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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	Mar-09-2021 11:20:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No data necessary as subject withdrawn from study <hr/> Not Applicable



**Header Text:** c4591001

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**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - Comments

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**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Mar-09-2021 11:20:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No data necessary as subject withdrawn from study Not Applicable
1	Feb-17-2021 14:28:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject not rejoining trial, but was contacted to be unblinded

**Header Text:** c4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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	Mar-09-2021 11:20:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No data necessary as subject withdrawn from study 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: 11401035

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 15:40:14 (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-17-2021 14:28:18 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Thomas	Approved	Jan-08-2021 10:01:29 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Dec-22-2020 11:34:09 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Thomas	Approved	Nov-13-2020 12:29:35 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**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-13-2020 10:46:04 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Thomas	Approved	Oct-13-2020 20:11:53 (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 10:57:06 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Thomas	Approved	Oct-11-2020 20:37:40 (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.

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

(b) (6)	N/A	Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Thomas	Approved	Sep-24-2020 08:30:45 (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.

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1140

**Subject No:** 11401035

**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
Aug-05-2020 10:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 10:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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
Aug-05-2020 10:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/4/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-05-2020 10:04:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11401035	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-05-2020 10:04:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1958	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-05-2020 10:06:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-05-2020 10:06:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 10:06:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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-13-2020 06:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Per site confirmation
Aug-12-2020 12:02:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Please see the updated data
Aug-07-2020 07:25:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	DM Query: Kindly review and complete 'REACTOGENICITY DIARY' form at this visit. Thank you
Aug-05-2020 10:07:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/4/2020	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

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
Aug-05-2020 10:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/4/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-05-2020 10:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-05-2020 10:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

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
Aug-07-2020 08:28:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> hypertension <b>Start Date:</b> Jan/UNK/2012 <b>Ongoing:</b> YES	Changed Information
Aug-05-2020 10:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> HTN <b>Start Date:</b> Jan/UNK/2012 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-05-2020 10:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 08:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-07-2020 08:28:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-07-2020 08:28:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> hypertension	Changed Information
Aug-06-2020 20:29:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please can you avoid using abbreviations to avoid ambiguity.

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

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

				Please update the following term: HTN
Aug-05-2020 10:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HTN	Initial Entry

**I.a Start Date:**

Date	Location	User	Value	Reason
Aug-05-2020 10:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/UNK/2012	Initial Entry

**I.a Ongoing:**

Date	Location	User	Value	Reason
Aug-05-2020 10:08:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Aug-05-2020 10:09:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> High cholesterol <b>Start Date:</b> Jan/UNK/2012 <b>Ongoing:</b> YES	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

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.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-05-2020 10:09:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 10:09:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> High cholesterol	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Aug-05-2020 10:09:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/UNK/2012	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Aug-05-2020 10:09:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Aug-05-2020 10:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> GERD <b>Start Date:</b> Aug/UNK/2019 <b>Ongoing:</b> YES	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

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
Aug-05-2020 10:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 10:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> GERD	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-05-2020 10:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/UNK/2019	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-05-2020 10:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-05-2020 10:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number 4 : Medical History T Peritonsillar abs cess Start Date: UNK/UNK/198 4 Ongoing: NO End Date:  UNK/UNK/1 984	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-05-2020 10:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 10:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Peritonsillar abscess	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Aug-05-2020 10:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1984	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Aug-05-2020 10:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1984	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Aug-05-2020 10:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: r: Medical History Deviated septum repair Term: Start Date: UNK/UNK/2009 Ongoing: NO End Date:  UNK/UNK/2009	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

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
Aug-05-2020 10:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-05-2020 10:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Deviated septum repair	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Aug-05-2020 10:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2009	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Aug-05-2020 10:14:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2009	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Aug-07-2020 08:29:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Line/MH Num 6 <b>ber:</b> <b>Medical Histor</b> Fever of Unknown <b>y Term:</b> Origin <b>Start Date:</b> UNK/UNK/2012 <b>Ongoing:</b> NO End Date:  UNK/UNK/2012	Changed Information

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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

Aug-05-2020 11:30:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>r:</b> <b>Medical History:</b> FUO <b>Term:</b> <b>Start Date:</b> UNK/UNK/2012 <b>Ongoing:</b> NO End Date: UNK/UNK/2012	Initial Entry
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090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

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

**If Line/MH Number:**

Date	Location	User	Value	Reason
Aug-05-2020 11:30:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-11-2020 08:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-07-2020 08:29:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-07-2020 08:29:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Fever of Unknown Origin	Changed Information
Aug-06-2020 20:30:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please can you avoid using abbreviations to avoid ambiguity. Please update the following term: FUO
Aug-05-2020 11:30:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FUO	Initial Entry

**If Start Date:**

Date	Location	User	Value	Reason
Aug-05-2020 11:30:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2012	Initial Entry

**If Ongoing:**

Date	Location	User	Value	Reason
Aug-05-2020 11:30:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: UNK/UNK/2012	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

I.g

Date	Location	User	Value	Reason
Aug-07-2020 08:30:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> (+) purified protein derivative <b>Start Date:</b> UNK/UNK/1984 <b>Ongoing:</b> NO End Date: UNK/UNK/1984	Changed Information
Aug-05-2020 11:30:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>r:</b> <b>Medical History Term:</b> (+) PPD <b>Start Date:</b> UNK/UNK/1984 <b>Ongoing:</b> NO End Date: UNK/UNK/1984	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Aug-05-2020 11:30:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Oct-08-2020 20:15:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 2: Closed	Response satisfies query
Oct-08-2020 15:45:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	Ideopathic Urticaria added to med history. There is no SAE for this subject.
Oct-07-2020 18:05:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 2: Opened	As per SAE, idiopathic urticaria is pre-existing on med hx. Please confirm and enter. Thanks
Aug-11-2020 08:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-07-2020 08:30:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Aug-07-2020 08:30:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> (+) purified protein derivative	Changed Information
Aug-06-2020 20:31:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please can you avoid using abbreviations to avoid ambiguity. Please update the following term: (+) PPD

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

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

Date	Location	User	Value	Reason
Aug-05-2020 11:30:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> (+) PPD	Initial Entry

*I.g Start Date:*

Date	Location	User	Value	Reason
Aug-05-2020 11:30:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1984	Initial Entry

*I.g Ongoing:*

Date	Location	User	Value	Reason
Aug-05-2020 11:30:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/1984	Initial Entry

*I.h*

Date	Location	User	Value	Reason
Oct-08-2020 15:45:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8 <b>Medical History Term:</b> Idiopathic Urtic aria <b>Start Date:</b> UNK/UNK/200 8 <b>Ongoing:</b> YES	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

***1.h Line/MH Number:***

Date	Location	User	Value	Reason
Oct-08-2020 15:45:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

***1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Oct-08-2020 15:45:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Idiopathic Urticaria	Initial Entry

***1.h Start Date:***

Date	Location	User	Value	Reason
Oct-08-2020 15:45:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2008	Initial Entry

***1.h Ongoing:***

Date	Location	User	Value	Reason
Oct-08-2020 15:45:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401035

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-05-2020 10:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/4/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-05-2020 10:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 202.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-05-2020 10:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-05-2020 10:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 69.6	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-05-2020 10:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-05-2020 10:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 29.3	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401035

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

7.a

Date	Location	User	Value	Reason
Aug-05-2020 10:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier:: 1 Temperature: 98.3 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-05-2020 10:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-05-2020 10:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-05-2020 10:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-05-2020 10:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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
Aug-05-2020 10:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/4/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-05-2020 10:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 222344	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: 11401035

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-05-2020 10:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-05-2020 10:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-07-2020 09:52:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-06-2020 02:47:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. Thank you.
Aug-05-2020 10:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-05-2020 10:28:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/4/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001  
 Visit: V1\_DAY1\_VAX1\_L  
 Form Version: 22-Apr-2020 21:03  
 Site No: 1140  
 Subject No: 11401035  
 Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
 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-07-2020 09:52:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPG596	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-07-2020 09:52:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BPG596	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Aug-07-2020 09:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPG597	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-07-2020 09:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BPG597	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-07-2020 09:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNB44R	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-07-2020 09:53:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BNB44R	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-07-2020 09:53:27 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNB44S	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
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5.d Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 09:53:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BNB44S	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-07-2020 09:53:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNB44T	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 09:53:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BNB44T	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

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-05-2020 10:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-05-2020 10:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-07-2020 11:16:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-06-2020 02:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. Thank you.
Aug-05-2020 10:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-05-2020 10:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/4/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Aug-07-2020 11:16:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNB44N	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-07-2020 11:16:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BNB44N	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401035

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-05-2020 10:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-05-2020 10:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-05-2020 10:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-05-2020 10:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/4/2020 15:01	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-05-2020 10:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-05-2020 10:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

**7. Route:**

Date	Location	User	Value	Reason
Aug-05-2020 10:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-05-2020 10:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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-05-2020 10:29:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1140

**Subject No:** 11401035

**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](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-07-2020 09:23:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-26-2020 11:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

*2. Erroneous Visit*

Date	Location	User	Value	Reason
Aug-26-2020 11:39:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	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: 11401035

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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Do ne  <b>Were fever or systemic symp</b> Not <b>toms present on the last day t</b> Do <b>he Subject Diary was comple</b> ne <b>ted?:</b>	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

*2.b*

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Do ne	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Done	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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> Not Do ne  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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Done	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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

2.d

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Do ne  <b>Were fever or systemic symp</b> Not <b>toms present on the last day t</b> Do <b>he Subject Diary was comple</b> ne <b>ted?:</b>	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Do ne  <b>Were fever or systemic symp</b> Not <b>toms present on the last day t</b> Do <b>he Subject Diary was comple</b> ne <b>ted?:</b>	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

2.e Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Done  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Done	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

2.g

Date	Location	User	Value	Reason
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090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  Not Done  Not Done
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**2.g Symptom:**

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  Not Done  Not Done

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

**2.h Symptom:**

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Don e <b>Were injection site reactions</b> Not Don <b>present on the last day the S</b> Don <b>ubject Diary was completed?</b> e :	Initial Entry

**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
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090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	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-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Done  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not Done	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> Not Done	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

			Were injection site reactions present on the last day the Subject Diary was completed? e	
			Not Done	

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 11:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1140

Subject No: 11401035

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-26-2020 11:40:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Temperature:</b> Not Done <b>Temperature Unit:</b> Not Done <b>Temperature Location::</b> Not Done	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:13 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1140

**Subject No:** 11401035

**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

(US & Canada)				
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090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

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-26-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Aug-26-2020 11:40:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401035

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-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

**7. Route:**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	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-26-2020 11:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Sep/22/2020

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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
Nov-13-2020 11:12:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-13-2020 10:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Visit is after the Date of Completion/Discontinuation /Death on the Follow-Up Disposition form. Please review and update as appropriate.
Oct-09-2020 22:19:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-08-2020 15:49:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Subject was discontinued from study by provider discretion but per provider request returned to office for unscheduled follow up visit as the subject had already received one study drug dose
Sep-28-2020 20:09:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Please can you confirm why subject was called for UNPL visit? Subject does not have any AE's listed in the timeframe when called (22 Sep) Thanks
Sep-25-2020 13:28:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Sep/22/2020

**Form:** UNPLANNED VISIT - 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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

*I. Assessments*

Date	Location	User	Value	Reason
Sep-25-2020 13:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-25-2020 13:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Sep-25-2020 13:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/22/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

**I. Contact Type:**

Date	Location	User	Value	Reason
Sep-25-2020 13:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Sep-29-2020 04:46:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Sep-28-2020 11:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Data has been updated.
Sep-26-2020 05:09:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate. Thank you.
Sep-25-2020 13:29:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Sep-25-2020 13:29:29	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Sep/22/2020

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	YES Date of Contact: Sep/22/2020 Contact Outcome: VISIT ARRANGED	
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**3. Comments:**

Date	Location	User	Value	Reason
Sep-25-2020 13:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Subject attended clinic visit for safety check after subject treatment was discontinued prior to receiving second injection. Subject will continue to complete study visits going forward.	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Sep/22/2020

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

[Back to Form](#)

**I. Date:**

Date	Location	User	Value	Reason
Sep-25-2020 13:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-25-2020 13:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.6 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-25-2020 13:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-25-2020 13:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 98.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-25-2020 13:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Sep/22/2020

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Sep-25-2020 13:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/22/2020

Form Version: 15-Sep-2020 21:51

Site No: 1140

Subject No: 11401035

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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 Assessment:**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Injection Site Location**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Injection Site Body Side:**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Reaction::</b> Not Applicable <b>Reaction Present::</b> Not Applicable	Initial Entry

**4.a Reaction:**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4.a Reaction Present:**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/22/2020

Form Version: 15-Sep-2020 21:51

Site No: 1140

Subject No: 11401035

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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

4.b

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Reaction::</b> Not Applicable <b>Reaction Present::</b> Not Applicable	Initial Entry

4.b Reaction:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable <b>Symptom Present::</b> Not Applicable	Initial Entry

5.a Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Symptom Present:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/22/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable <b>Symptom Present::</b> Not Applicable	Initial Entry

5.b Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable <b>Symptom Present::</b> Not Applicable	Initial Entry

5.c Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
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090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)



Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/22/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable <b>Symptom Present::</b> Not Applicable	Initial Entry
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5.d Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> Not Applicable <b>Symptom Present::</b> Not Applicable	Initial Entry

5.e Symptom:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Sep/22/2020

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1140

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

**Subject No:** 11401035

**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)	<b>Symptom::</b> Not Applicable <b>Symptom Present::</b> Not Applicable	
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**5.f Symptom:**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Symptom Present:**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable <b>Symptom::</b> Not Applicable <b>Symptom Present::</b> Not Applicable	Initial Entry

**5.g Symptom:**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Symptom Present:**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable <b>Symptom::</b> Not Applicable	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Sep/22/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - 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>Symptom Present::</b> Not Applicable	
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**5.h Symptom:**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Symptom Present:**

Date	Location	User	Value	Reason
Sep-25-2020 13:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 22-Apr-2020 21:05

Site No: 1140

Subject No: 11401035

Generated By: (b) (4)

Form: DISPOSITION - 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](#)

**I. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-13-2020 02:24:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	As per site confirmation
Nov-11-2020 15:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	Per source documentation, the subject contacted the site to withdraw consent on 22Sep2020, which is after the End Date of the AE. Confirmed that the date entered is correct.
Nov-10-2020 22:48:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Opened	The discontinuation date of 22SEP2020 should be relative to the AE causing the the withdrawal of the study vaccine, AE start 13AUG2020 and end 13AUG2020 (date should not be after the AE ended). Please adjust Discontinuation date.
Oct-13-2020 14:29:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-13-2020 10:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-13-2020 10:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	New Information
Oct-09-2020 15:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Opened	DM: Please confirm if subject is continuing in study. If not, please enter the FUP form as well.

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:05

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

Aug-26-2020 11:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry
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2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-26-2020 11:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-13-2020 14:40:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-13-2020 13:33:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> ADVERSE EVENT	Changed Information
Oct-13-2020 10:58:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	AE updated to reflect the reasoning for discontinuation
Oct-09-2020 10:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Ahmed Hassan (b) (4)	Query 1: Reissued:Opened	Please review CRF completion requirements (8.55.2- section pertaining to discontinuation, if there are more than 1 reason for discontinuation, and AE is one of the reasons), and update as appropriate. thanks
Oct-08-2020 15:51:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Related to AE urticaria. Subject has spontaneous allergic reactions of unknown cause. As the subject has been worked up by PCP and no exact allergy has been established, the physician did not feel comfortable

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 22-Apr-2020 21:05

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** DISPOSITION - 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

				continuing to administer a research drug
Sep-28-2020 21:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	ClinQuery: Subject was withdrawn due to Physician decision. Please can you review and confirm if this is related to an AE? If so, update as appropriate. Thanks
Aug-26-2020 11:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> PHYSICIAN DECISION	Initial Entry

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1140

Subject No: 11401035

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-13-2020 14:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 11:12:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Changed Information
Nov-13-2020 10:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per query
Nov-13-2020 10:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Aug/13/2020	updated per query
Nov-12-2020 01:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM :Status is recorded as ADVERSE EVENT. for AE ( 13AUG2020 - 13AUG2020) , action taken with study treatment is DRUG WITHDRAWN. However, Date of discontinuation(22/Sep /2020) is after the AE end date. Please review and update with CRA's help.
Nov-11-2020 15:35:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Per source documentation, the subject contacted the site to withdraw consent on 22Sep2020, which is after the End Date of the AE. Confirmed that the date entered is correct.
Nov-10-2020 22:48:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	The discontinuation date of 22SEP2020 should be relative to the AE causing the the withdrawal of the study

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

				vaccine, AE start 13AUG2020 and end 13AUG2020 (date should not be after the AE ended). Please adjust Discontinuation date.
Oct-13-2020 14:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-13-2020 14:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-13-2020 14:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401035

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
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> urticaria	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Aug/13/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Aug/13/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401035

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

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-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-07-2020 13:05:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Clin: Query to be moved to appropriate page
Oct-06-2020 18:03:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Once page is unlocked please enter the appropriate pre-existing medical condition on the medical history page
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s) , this event is due to:  OTHER  If Other, specify:  idiopathic urticaria (pre-existing on med hx)	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> DRUG WITHDRAWN	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 14:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 10:57:40 (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.

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1140

**Subject No:** 11401035

**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

Oct-13-2020 10:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information
Sep-25-2020 13:21:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401035

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
Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Medication Error (Type of Medication Error):**

Date	Location	User	Value	Reason
Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Start Date:**

Date	Location	User	Value	Reason
Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Is the medication error still ongoing?**

Date	Location	User	Value	Reason
Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401035

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
Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

8. Did the Medication Error cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

9. Was this medication error associated with any adverse events?

Date	Location	User	Value	Reason
Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

10. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-08-2020 15:46:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

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
Oct-08-2020 15:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-08-2020 15:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-08-2020 15:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Oct-08-2020 15:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-08-2020 15:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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[Back to Form](#)

Date	Location	User	Value	Reason
Sep-30-2020 10:09:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Deleted	Does not meet criteria for con/med reporting
Sep-25-2020 13:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

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

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

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

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Sep-25-2020 13:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Sep-25-2020 13:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> CORTICOSTEROIDS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Sep-25-2020 13:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

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

Date	Location	User	Value	Reason
Oct-01-2020 05:46:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-30-2020 10:09:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Agreed, will delete entry
Sep-28-2020 21:52:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	ClinQuery: Prednisone: Please note this medication doesn't meet the dose/duration criteria specified in section 6.5.1. Please update

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

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

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

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

				as appropriate. Thanks
Sep-25-2020 13:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Prednisone	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Sep-25-2020 13:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 60	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Sep-25-2020 13:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Sep-25-2020 13:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Sep-25-2020 13:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Sep-25-2020 13:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

10. Ongoing?

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

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

**Site No:** 1140

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

**Subject No:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

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

Date	Location	User	Value	Reason
Sep-25-2020 13:25:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Aug/23/2020	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401035

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
Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Oct-08-2020 15:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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
Oct-08-2020 15:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

***2. Date of Transfusion:***

Date	Location	User	Value	Reason
Oct-08-2020 15:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

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
Mar-09-2021 17:24:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Clo sed	Response satisfies query
Mar-09-2021 11:20:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 9: Ans wered	Changed data per query
Mar-09-2021 11:20:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : Not A pplica ble	Initial Entry
Mar-09-2021 00:38:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 9: Op ened	DM: If there is no data needs to be reported on this page, kindly consider marking form as Not Applicable by selecting form level comment or else update the details. Thank you.
Mar-08-2021 14:40:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Clo sed	Response satisfies query
Mar-08-2021 08:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Ans wered	Changed Information

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Mar-08-2021 08:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> :	Changed Information
Mar-05-2021 10:41:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Op ened	Since the subject was unblinded AFTER discontinuing the study the unblinding should be recorded in source only and not the CRF. Please mark this visit ERRONEOUS and remove the data from this form else clarify.
Mar-05-2021 10:40:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Clo sed	REWORD
Mar-04-2021 17:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 7: Rei ssued: Opene d	Reopen: 'Date Treatment Unblinded' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Mar-04-2021 10:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Ans wered	Transcription Error
Mar-04-2021 10:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Clo sed	Close Auto Query
Mar-04-2021 10:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : Dec/2 1/202 0	Transcription Error

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

Mar-02-2021 08:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 7: Op ened	DMW7565890;'Date Treatment Unblinded' is after 'Date of Completion/Discontinuation '/Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Mar-02-2021 03:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (b) (4)	Query 5: Clo sed	Response satisfies query
Mar-01-2021 16:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Op ened	Response to "Date Treatment Unblinded" 21/Dec/2021 is a future date relative to when it was entered on 01/Mar/2021. Please correct.
Mar-01-2021 16:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Ans wered	Initial Entry
Mar-01-2021 16:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : Dec/2 1/202 1	Initial Entry
Feb-22-2021 02:06:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 5: Op ened	DM: If there is no data expected to be enter on this form then kindly consider marking this form as Not Applicable by selecting form level comment or else update details. Thank you.
Feb-19-2021 17:24:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Clo sed	data cleared

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

Feb-19-2021 17:24:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 4: Clo sed	data cleared
Feb-19-2021 14:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Ans wered	UPDATED PER QUERY REQUEST
Feb-19-2021 14:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ans wered	UPDATED PER QUERY REQUEST
Feb-19-2021 14:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> :	UPDATED PER QUERY REQUEST
Feb-18-2021 02:03:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Op ened	CLINQUERY: Form level comments (speech bubble) to be used to add an entry for Not Done/Not Applicable (subject not re-joining trial)
Feb-17-2021 16:42:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Rei ssued: Opene d	CLINQUERY: Form remains completed. please add form level comments (speech bubble) to be used to add an entry for Not Done/Not Applicable (if subject not re-joining trial and unblind performed post end of study)
Feb-17-2021 14:28:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Ans wered	Changed data per query

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

Feb-16-2021 12:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 4: Can didate	CLINQUERY: Form level comments (speech bubble) to be used to add an entry for Not Done/Not Applicable (subject not re-joining trial)
Feb-16-2021 12:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Rei ssued: Opene d	CLINQUERY: Form level comments (speech bubble) to be used to add an entry for Not Done/Not Applicable (subject not re-joining trial)
Feb-16-2021 12:05:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Ans wered	Subject not re-joining. Please advise on how to remove unblinding information from eCRF. Unable to delete.
Feb-15-2021 23:40:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Op ened	CLINQUERY: Please confirm if subject is re-joining the trial for revaccination. If not re-joining, please only capture treatment unblind in source. Data cannot be entered in CRF post Disp FUP date (end of study)
Feb-15-2021 18:30:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Can didate	CLINQUERY: Please confirm if subject is re-joining the trial for revaccination. If not re-joining, please only capture treatment unblind in source. Data cannot be entered in CRF post Disp FUP date (end of study)
Jan-06-2021 05:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Closed as data updated.
Jan-05-2021 16:08:19 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Ans wered	updated per query

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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:** 11401035

**Subject Initials:** ---

**Generated By:** (b) (4)

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

Eastern Time (US & Canada)				
Dec-24-2020 01:23:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-24-2020 00:09:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM1: Per eCCG section 8.65.2 confirm if reason for unblinding is 'ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION' . If yes, then consider updating Primary Reason for Unblinding accordingly. Else, clarify.
Dec-23-2020 13:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	This was to date/record the treatment unblinding purposes only.
Dec-23-2020 13:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	This was to date/record the treatment unblinding purposes only. No further actions/visits were conducted post discontinuation date
Dec-23-2020 02:44:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (b) (4)	Query 2: Opened	IVRS Reconciliation: BLIND BROKEN? in IMPALA is NO but TREATMENT UNBLINDED form has been completed in InForm. Please review and update as appropriate. Else, clarify. Thank you.
Dec-22-2020 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6588833;'Date Treatment Unblinded' is after 'Date of Completion/Discontinuation /Death' on the Disposition -

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (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: 11401035

Subject Initials: ---

Generated By: (b) (4)

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

Canada)				Follow-up eCRF. Please clarify or correct.
Dec-22-2020 11:34:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : Dec/21/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-09-2021 11:20:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Mar-08-2021 08:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Mar-02-2021 02:15:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed considering unblinding date is post to FU_Dispo date
Mar-02-2021 01:54:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	IVRS Reconciliation: Other is selected as the primary reason for unblinding but matching blind break is not captured in IRT. Please correct primary reason in Inform or confirm as correct".
Mar-01-2021 16:17:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> OTHER <i>If other, specify:</i>  Subject discontinued from study, but is MD and wished to be unblinded	Initial Entry
Feb-19-2021 14:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b>	REMOVED DATA PER QUERY REQUEST
Jan-07-2021 02:07:39 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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

Time (US & Canada)				
Jan-05-2021 16:07:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per query
Jan-05-2021 16:07:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	updated per query

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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](#)

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Dec-23-2020 19:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Subject is listed to be unblinded due to subject safety concern, however, there are no AE's around the time of unblinding. Please review/confirm as appropriate. Thanks
Dec-22-2020 11:34:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> SUBJECT SAFETY CONCERN	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401035

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](#)

***1. Subject Status***

Date	Location	User	Value	Reason
Oct-13-2020 14:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-13-2020 13:33:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Aug-26-2020 11:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Aug-05-2020 10:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-05-2020 10:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

***2. Subject Status Date***

Date	Location	User	Value	Reason
Nov-13-2020 11:12:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/22/2020	Changed Information
Nov-13-2020 10:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/13/2020	updated per query
Oct-13-2020 14:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/22/2020	Initial Entry
Oct-13-2020 13:33:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/22/2020	Changed Information
Oct-13-2020 10:57:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/22/2020	New Information
Aug-26-2020 11:38:06 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1140

**Subject No:** 11401035

**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

(US & Canada)				
Aug-05-2020 10:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/4/2020	Initial Entry
Aug-05-2020 10:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/4/2020	Initial Entry

090177e196ae30f3\Final\Final On: 01-Apr-2021 04:20 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1140

**Subject No:** 11401035

**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
Sep-24-2020 08:15:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry