

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 10-Oct-2020 16:01

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

1.	Select appropriate response - Protocol version	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

<b>Header Text:</b> c4591001	<b>Form:</b> MAIN INFORMED CONSENT
<b>Visit:</b> COHORT_SELECTION	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1140) SUNY Upstate Medical University
<b>Site No:</b> 1140	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11401285	<b>Generated Time (GMT):</b> 29-Mar-2021 11:44
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/14/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DEMOGRAPHY

**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](#)

**Demography**

1.	Subject ID	[11401285]
2.	Birth Date:	(b) (6)/1965
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/14/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, 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
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**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DISPOSITION - SCREENING

**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 - Screening**

1.	Date of Completion/Discontinuation/Death	Oct/14/2020
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: 11401285

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

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](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Panic Attacks]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Psoriasis]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	Apr/UNK/2008
	Ongoing:	NO End Date: Apr/UNK/2008
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sulfa Drug Allergy]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** HIV STATUS

**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](#)

**HIV Status**

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
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**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** VITAL SIGNS - BASELINE

**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](#)

**Vital Signs**

1.	Date:	Oct/14/2020
2.	Weight:	[119.2]
3.	Unit:	LB
4.	Height:	[60.75]
5.	Unit:	in
6.	Body Mass Index:	[22.7]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 15:58

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, 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](#)

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** RANDOMIZATION

**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**

1.	Randomization Date :	Oct/14/2020
2.	Randomization Number:	[107216]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8D9T]
5.b	Sample ID	[BNWXPJ]
5.c	Sample ID	[BNWXPK]
5.d	Sample ID	[BNWXPL]

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**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYZCN]
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090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** VACCINATION

**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](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/14/2020 10:56
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** REACTOGENICITY DIARY

**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](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/4/2020
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** VITAL SIGNS - TEMP

**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](#)

**Vital Signs**

1.	Date:	Nov/4/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 15:58

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, 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](#)

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/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	[BP8DGX]
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090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** VACCINATION

**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](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Nov/4/2020 13:21
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/2/2020
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	[BP8DJF]
5.b	Sample ID	[BLGBRN]
5.c	Sample ID	[BLGBRP]

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS ONSET

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

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**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:** 11401285

**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:	[ ]
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**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:** 11401285

**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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090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**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:** 11401285

**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:	[ ]
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL - New Unscheduled Visit

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**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:** 11401285

**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 Visit

**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:** 11401285

**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\_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:** 11401285

**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:** 11401285

**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:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1140

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

**Subject No:** 11401285

**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	enlarged lymph node axilla (R)	Feb/4/2021 08:00	NO End Date Time: Feb/10/2021 08:00	<a href="#">Repeating Pages</a>

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

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[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)	[enlarged lymph node axilla (R)]
4.	Start Date Time:	Feb/4/2021 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/10/2021 08:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1140

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

**Subject No:** 11401285

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Medication Error**

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

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1140

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

**Subject No:** 11401285

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1140

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

**Subject No:** 11401285

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1140

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

**Subject No:** 11401285

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**Radiation Treatment**

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

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

**Unplanned Assessments**

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

**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:** 11401285

**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:** 11401285

**Subject Initials:** ---

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

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**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?	

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**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:** 11401285

**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:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DISPOSITION - TREATMENT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Data Complete, Verified

**Site No:** 1140

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

**Subject No:** 11401285

**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	Jan/7/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Data Complete

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2
----	---	--



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/13/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**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](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/13/2021
----	--------------	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**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 - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Jan/13/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, 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](#)

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/13/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8DPV]
5.b	Sample ID	[BNWXVF]
5.c	Sample ID	[BNWXVG]
5.d	Sample ID	[BNWXVH]

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**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](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/13/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8DPP]
-----	-----------	----------

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** VACCINATION

**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](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/13/2021 14:33
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

**Form Status:** Data Complete, Verified

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/11/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

**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 :	//
----	------------------------------	----

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DATE OF VISIT

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

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, 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](#)

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**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](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP8DWC]
-----	-----------	----------

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** VACCINATION

**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](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/3/2021 14:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)



**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DATE OF VISIT

**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](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** CONTACT OUTCOME

**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](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/10/2021
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1140

**Subject No:** 11401285

**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:** V104\_MONTH6

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1140

**Subject No:** 11401285

**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:** V105\_MONTH18

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Verified

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Mar/10/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/2/2020



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

**Casebook Signature Form**

1.	Casebook Signature	
----	--------------------	--

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**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
- CRF\_Sign\_1

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

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Oct-14-2020 14:54:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject with documented hysterectomy, pregnancy test not done
			Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject with documented hysterectomy, pregnancy test not done
			Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject with documented hysterectomy, pregnancy test not done
			Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject with documented hysterectomy, pregnancy test not done
			Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject with documented hysterectomy, pregnancy test not done <hr/> Not Applicable



**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5	Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject with documented hysterectomy, pregnancy test not done
			Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject with documented hysterectomy, pregnancy test not done
			Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject with documented hysterectomy, pregnancy test not done
			Not Applicable

**Header Text:** c4591001

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

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject with documented hysterectomy, pregnancy test not done
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Nov-04-2020 15:36:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Nov-04-2020 15:36:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Nov-04-2020 15:36:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Nov-04-2020 15:36:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Nov-04-2020 15:36:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
5	Nov-04-2020 15:36:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Nov-04-2020 15:36:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Nov-04-2020 15:36:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Nov-04-2020 15:36:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Jan-13-2021 16:32:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Jan-13-2021 16:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Jan-13-2021 16:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Jan-13-2021 16:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Jan-13-2021 16:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

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**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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Item	Date	User	Comment
4	Jan-13-2021 16:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

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**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

**Subject Initials:** ---

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Item	Date	User	Comment
5	Jan-13-2021 16:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Jan-13-2021 16:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Jan-13-2021 16:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Jan-13-2021 16:33:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Feb-03-2021 16:17:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy ----- Not Applicable



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Feb-03-2021 16:17:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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Item	Date	User	Comment
2	Feb-03-2021 16:17:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

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**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

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Item	Date	User	Comment
3	Feb-03-2021 16:17:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

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**Site No:** 1140

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

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

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Item	Date	User	Comment
4	Feb-03-2021 16:17:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

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**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

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

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Item	Date	User	Comment
5	Feb-03-2021 16:17:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Feb-03-2021 16:17:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Feb-03-2021 16:17:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

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

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Feb-03-2021 16:17:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Subject had hysterectomy <hr/> Not Applicable



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Not Started

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Oct-14-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 14:51:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (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:** 11401285

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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***1. Consent Was:***

Date	Location	User	Value	Reason
Oct-14-2020 14:52:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Oct/14/2020	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Oct-14-2020 14:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11401285	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-14-2020 14:50:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1965	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-14-2020 14:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Oct-14-2020 14:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 14:52:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-14-2020 14:54:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Oct-14-2020 14:54:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-14-2020 14:54:27 (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
Oct-14-2020 14:54:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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*1.a*

Date	Location	User	Value	Reason
Oct-14-2020 14:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 Medical History Term: Panic Attacks Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-14-2020 14:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 14:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Panic Attacks	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Oct-14-2020 14:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2005	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
Oct-14-2020 14:55:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*1.b*

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** GENERAL MEDICAL HISTORY - 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

Date	Location	User	Value	Reason
Oct-14-2020 14:55:56 (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> Psoriasis <b>Start Date:</b> UNK/UNK/ 000 <b>Ongoing:</b> YES	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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

Date	Location	User	Value	Reason
Oct-14-2020 14:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Oct-22-2020 08:39:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gary Steven Friedman (b) (4)	Query 1: Closed	Response satisfies query
Oct-21-2020 11:04:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Subject is not receiving any oral CORTICOSTEROIDS OR METHOTREXATE or ORAL OR PARENTERAL IMMUNOMODULATORS currently.
Oct-19-2020 14:31:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Gary Steven Friedman (b) (4)	Query 1: Opened	PSORIASIS (ongoing): please confirm the participant IS or IS NOT receiving ORAL CORTICOSTEROIDS OR METHOTREXATE or ORAL OR PARENTERAL IMMUNOMODULATORS currently.
Oct-14-2020 14:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Psoriasis	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Oct-14-2020 14:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
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090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** GENERAL MEDICAL HISTORY - 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

Oct-14-2020 14:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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*I.c*

Date	Location	User	Value	Reason
Oct-14-2020 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number 3</b> : <b>Medical History T Hysterectomy</b> <b>erm:</b> <b>Start Date:</b> Apr/UNK/200 8 <b>Ongoing:</b> NO End Date:  Apr/UNK/2 008	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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

Date	Location	User	Value	Reason
Oct-14-2020 14:56:16 (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
Oct-14-2020 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Hysterectomy	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Oct-14-2020 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Apr/UNK/2008	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Oct-14-2020 14:56:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Apr/UNK/2008	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Oct-14-2020 15:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 4 : <b>Medical History T Sulfa Drug All</b> <b>erm:</b> ergy <b>Start Date:</b> UNK/UNK/19 90 <b>Ongoing:</b> YES	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - 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

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

Date	Location	User	Value	Reason
Oct-14-2020 15:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 15:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Sulfa Drug Allergy	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Oct-14-2020 15:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Oct-14-2020 15:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** HIV STATUS - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - What is the subject HIV status?*

Date	Location	User	Value	Reason
Oct-14-2020 14:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Oct-14-2020 14:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-14-2020 14:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 119.2	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Oct-14-2020 14:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Oct-14-2020 14:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 60.75	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Oct-14-2020 14:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Oct-14-2020 14:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 22.7	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - 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

7.a

Date	Location	User	Value	Reason
Oct-14-2020 14:57:43 (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> 97.0 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-14-2020 14:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-14-2020 14:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 97.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-14-2020 14:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-14-2020 14:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-14-2020 14:58:07 (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. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-14-2020 14:58:07 (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. Collection Date:**

Date	Location	User	Value	Reason
Oct-15-2020 21:16:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Raised by mistake.
Oct-15-2020 21:13:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: V1: Please can you confirm why a pregnancy test was not done for this subject? There is nothing in her medhx to indicate she is not a woman of child bearing potential. Update MedHx as appropriate. Thanks
Oct-14-2020 14:58:07 (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. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
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090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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5. Specimen Type:

Date	Location	User	Value	Reason
Oct-14-2020 14:58:07 (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.a

Date	Location	User	Value	Reason
Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> Not Applicable <b>entifier:</b> <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-14-2020 14:58:07 (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.a Test:

Date	Location	User	Value	Reason
Oct-14-2020 14:58:07 (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.a Result:

Date	Location	User	Value	Reason
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090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

Oct-14-2020 14:58:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**6.a Not Done:**

Date	Location	User	Value	Reason
Oct-14-2020 14:58:07 (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:** V1\_DAY1\_VAX1\_L

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-14-2020 14:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-14-2020 14:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 107216	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, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 14:58:43 (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
Oct-14-2020 14:58:43 (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
Oct-15-2020 11:25:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020 04:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 14:58:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 14:58:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/14/2020	Initial Entry

5.a

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-15-2020 11:25:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP8D9T</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 11:25:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BP8D9T	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-15-2020 11:26:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BNWXPJ</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 11:26:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BNWXPJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 11:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BNWXPJ</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 11:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BNWXPJ	Initial Entry

5.d

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Oct-15-2020 11:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNWXPL	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-15-2020 11:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BNWXPL	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-14-2020 14:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-14-2020 14:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-15-2020 11:26:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020 04:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 14:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 14:58:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> YES Date of Collection:  Oct/14/2020	Initial Entry

5.a

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Oct-15-2020 11:26:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPYZCN	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-15-2020 11:26:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BPYZCN	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:09 (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
Oct-14-2020 14:59:09 (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
Oct-14-2020 14:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Oct/14/2020 10:56	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-14-2020 14:59:09 (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
Oct-14-2020 14:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: VACCINATION - 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

7. Route:

Date	Location	User	Value	Reason
Oct-14-2020 14:59:09 (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
Oct-14-2020 14:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION 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
Oct-14-2020 14:59:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-14-2020 14:59:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-04-2020 15:22:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Nov-04-2020 15:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-04-2020 15:35:43 (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> 97.8 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-04-2020 15:35:43 (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
Nov-04-2020 15:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 97.8	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-04-2020 15:35:43 (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:**

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** VITAL SIGNS - TEMP - 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

Date	Location	User	Value	Reason
Nov-04-2020 15:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:29 (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. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:29 (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. Collection Date:**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:29 (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. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:29 (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. Specimen Type:**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:29 (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.a**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:29 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:29 (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.a Test:**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:29 (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.a Result:**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:29 (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.a Not Done:**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-04-2020 15:23:21 (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
Nov-04-2020 15:23:21 (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
Nov-04-2020 15:23:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 15:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-04-2020 15:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/4/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-04-2020 15:23:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP8DGX</b>	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-04-2020 15:23:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BP8DGX	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:54 (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
Nov-04-2020 15:36:54 (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
Nov-04-2020 15:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Nov/4/2020 13:21	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-04-2020 15:36:54 (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
Nov-04-2020 15:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: VACCINATION - 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

7. Route:

Date	Location	User	Value	Reason
Nov-04-2020 15:36:54 (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
Nov-04-2020 15:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION 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
Nov-04-2020 15:36:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Dec-08-2020 04:22:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-07-2020 15:59:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-03-2020 05:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.
Dec-02-2020 16:20:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-02-2020 16:20:58 (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
Dec-02-2020 16:20:58 (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
Dec-03-2020 14:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-02-2020 16:20:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-02-2020 16:20:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/2/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-03-2020 14:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP8DJF	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 14:08:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BP8DJF	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-03-2020 14:09:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLGBRN	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 14:09:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BLGBRN	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-03-2020 14:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLGBRP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 14:09:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BLGBRP	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Feb-05-2021 14:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Feb-05-2021 14:22:08 (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
Feb-05-2021 14:22:08 (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
Feb-05-2021 14:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> enlarged lymph node axilla (R)	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-05-2021 14:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021 08:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Mar-10-2021 14:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Feb/10/2021 08:00	New Information
Feb-05-2021 14:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-05-2021 14:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-05-2021 14:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> 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
Feb-05-2021 14:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-05-2021 14:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-05-2021 14:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-05-2021 14:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-05-2021 14:22:08 (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
Mar-10-2021 14:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-10-2021 14:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLV ED	New Information
Mar-10-2021 14:29:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE enlarged lymph node axilla (R): Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Feb-18-2021 01:08:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-17-2021 15:05:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-17-2021 15:05:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NO T RESOLVED	Initial Entry
Feb-17-2021 01:34:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opene d	As per your response please consider to update to RECOVERING/RESOLVING

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

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

**Subject Initials:** ---

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

				or NOT RECOVERED/NOT RESOLVED or RECOVERED/RESOLVED WITH SEQUELAE as appropriate. Or clarify.
Feb-16-2021 11:37:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	AE is ongoing, will re-assess at next scheduled subject contact.
Feb-08-2021 06:36:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "What was the outcome of this adverse event?" is missing. Kindly review and update.

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

Date	Location	User	Value	Reason
Feb-05-2021 14:22:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Dec-03-2020 14:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Dec/2/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-03-2020 14:07:29 (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
Dec-03-2020 14:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-10-2021 16:25:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jan/7/2021	Changed Information
Jan-13-2021 16:31:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail  
History

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

**Form Status:** Data Complete

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

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

Date	Location	User	Value	Reason
Mar-10-2021 16:25:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return fo r Vaccination 3 Participant is:  eligible per other protocol all owance(s) and confirmed to h ave received only placebo at Vaccination 1/2	Changed Information
Jan-13-2021 16:31:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 16:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-13-2021 16:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return fo r Vaccination 3 Participant is:  eligible per local/national rec ommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-13-2021 16:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jan/13/2021	Initial Entry



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

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**1. Consent Was:**

Date	Location	User	Value	Reason
Jan-13-2021 16:32:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/13/2021	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-13-2021 16:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-13-2021 16:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-13-2021 16:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:23 (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. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:23 (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. Collection Date:**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:23 (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. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:23 (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. Specimen Type:**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:23 (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.a**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:23 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:23 (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.a Test:**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:23 (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.a Result:**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:23 (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.a Not Done:**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:41 (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
Jan-13-2021 16:33:41 (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
Jan-14-2021 13:11:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 16:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-13-2021 16:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/13/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-14-2021 13:11:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP8DPV</b>	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Jan-14-2021 13:11:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BP8DPV	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-14-2021 13:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNWXVF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-14-2021 13:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BNWXVF	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-14-2021 13:12:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNWXVG	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-14-2021 13:12:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BNWXVG	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-14-2021 13:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNWXVH	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

**5.d Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-14-2021 13:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BNWXVH	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-13-2021 16:33:54 (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
Jan-13-2021 16:33:54 (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
Jan-14-2021 13:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 16:33:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-13-2021 16:33:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/13/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-14-2021 13:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP8DPP	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-14-2021 13:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BP8DPP	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-13-2021 16:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-13-2021 16:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-13-2021 16:34:27 (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
Jan-13-2021 16:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Jan/13/2021 14:33	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-13-2021 16:34:27 (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
Jan-13-2021 16:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: VACCINATION - 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

7. Route:

Date	Location	User	Value	Reason
Jan-13-2021 16:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-13-2021 16:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-13-2021 16:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-13-2021 16:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 16:34:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

**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

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Mar-10-2021 22:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_36
Mar-10-2021 16:25:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-10-2021 16:25:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : Jan/11/2021	Changed Information
Feb-23-2021 12:17:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7352597;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Jan-13-2021 16:31:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : Jan/7/2021	Initial Entry

**2. Primary Reason for Unblinding:**

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

**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

Date	Location	User	Value	Reason
Jan-13-2021 16:31:56 (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	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-03-2021 16:17:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-03-2021 16:17:49 (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. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-03-2021 16:17:49 (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. Collection Date:**

Date	Location	User	Value	Reason
Feb-03-2021 16:17:49 (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. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-03-2021 16:17:49 (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. Specimen Type:**

Date	Location	User	Value	Reason
Feb-03-2021 16:17:49 (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.a**

Date	Location	User	Value	Reason
Feb-03-2021 16:17:49 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test:</b> Not Applicable <b>Result:</b> Not Applicable <b>Not Done:</b> Not Applicable
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-03-2021 16:17:49 (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.a Test:**

Date	Location	User	Value	Reason
Feb-03-2021 16:17:49 (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.a Result:**

Date	Location	User	Value	Reason
Feb-03-2021 16:17:49 (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.a Not Done:**

Date	Location	User	Value	Reason
Feb-03-2021 16:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)



Header Text: c4591001

Visit: V102\_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401285

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-03-2021 16:18:25 (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
Feb-03-2021 16:18:25 (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
Feb-03-2021 16:31:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 16:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-03-2021 16:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/3/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-03-2021 16:31:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP8DWC</b>	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

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

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

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-03-2021 16:31:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> BP8DWC	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-03-2021 16:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-03-2021 16:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-03-2021 16:19:04 (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
Feb-03-2021 16:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Feb/3/2021 14:40	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-03-2021 16:19:04 (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
Feb-03-2021 16:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1140

Subject No: 11401285

Generated By: (b) (4)

Form: VACCINATION - 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

7. Route:

Date	Location	User	Value	Reason
Feb-03-2021 16:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-03-2021 16:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-03-2021 16:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-03-2021 16:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021 16:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** DATE OF VISIT - 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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-10-2021 14:28:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Mar/10/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1140

**Subject No:** 11401285

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

**Form:** CONTACT OUTCOME - 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

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**1. Contact Type:**

Date	Location	User	Value	Reason
Mar-10-2021 14:28:25 (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
Mar-10-2021 14:28:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Mar/10/2021	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Verified

**Site No:** 1140

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

**Subject No:** 11401285

**Subject Initials:** ---

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

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-10-2021 14:29:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Mar/10/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-10-2021 14:29:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-10-2021 14:29:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1140

**Subject No:** 11401285

**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

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***1. Subject Status***

Date	Location	User	Value	Reason
Dec-03-2020 14:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-14-2020 14:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-14-2020 14:54:27 (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
Dec-03-2020 14:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/2/2020	Initial Entry
Oct-14-2020 14:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	Initial Entry
Oct-14-2020 14:54:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/14/2020	Initial Entry

090177e196ae30f6\Final\Final On: 01-Apr-2021 04:21 (GMT)