

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/19/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11401156]
2.	Birth Date:	(b) (6) 1946
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/19/2020
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: 11401156

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery Bypass Graft]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2012
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Atherosclerotic Cardiovascular Artery Disease]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Pacemaker]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergy]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypercholesterol]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gout]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/19/2020
2.	Weight:	[234.0]
3.	Unit:	LB
4.	Height:	[69.7]
5.	Unit:	in
6.	Body Mass Index:	[33.9]

Vital Signs Details

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

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/19/2020
2.	Randomization Number:	[231891]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/19/2020
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	[BPG5JP]
5.b	Sample ID	[BPG5JR]
5.c	Sample ID	[BPYZNR]
5.d	Sample ID	[BPYZNS]
5.e	Sample ID	[BPYZNT]

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/19/2020
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	[BPYZNL]
-----	-----------	----------

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/19/2020 12:55
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	--	--

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/9/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/9/2020
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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: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/9/2020
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	[BPYZ36]
-----	-----------	----------

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/9/2020 13:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/7/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
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	[BP8D8D]
5.b	Sample ID	[BPG5RM]
5.c	Sample ID	[BPG5RN]
5.d	Sample ID	[BPG5RP]

090177e196ae30fb\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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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

090177e196ae30fb\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: 11401156

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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled 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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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 :	Oct/7/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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: 11401156

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	Aortic Valve Dysfunction	Oct/1/2020 UNK: UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	pain at injection site	Feb/9/2021 09:00	NO End Date Time: Feb/10/2021 11:00	Repeating Pages

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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[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)	[Aortic Valve Dysfunction]
4.	Start Date Time:	Oct/1/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [pre-existing medical history]

090177e196ae30fb\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

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Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021131934]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[pain at injection site]
4.	Start Date Time:	Feb/9/2021 09:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/10/2021 11:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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	[]

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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: 11401156

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1140

Subject No: 11401156

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	[]

090177e196ae30fb\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: 11401156

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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:	//

090177e196ae30fb\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: 11401156

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

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?	

090177e196ae30fb\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: 11401156

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.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

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

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Radiation Treatment

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

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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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

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 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: 11401156

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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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?	

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: 11401156

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: 11401156

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: 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: 11401156

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/6/2021
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: 11401156

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: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/12/2021
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: 11401156

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 :	//
----	------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

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/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1140

Subject No: 11401156

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 Feb/8/2021
----	--------------	---

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: 11401156

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: 11401156

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 :	Feb/8/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

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: Feb/8/2021
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	[BRFJBY]
5.b	Sample ID	[BSGRC2]
5.c	Sample ID	[BSGRC3]

090177e196ae30fb\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: 11401156

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/8/2021
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	[BP8DYG]
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090177e196ae30fb\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: 11401156

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/8/2021 12:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30fb\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: 11401156

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	Mar/1/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

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: Mar/1/2021
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	[BRFJHY]
-----	-----------	----------

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1140

Subject No: 11401156

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:	Mar/1/2021 11:57
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30fb\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: 11401156

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: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401156

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: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

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: 11401156

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: 11401156

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: 11401156

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: Not Started

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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	Oct/7/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Stephen Thomas	Approved	Mar-12-2021 15:37:33 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Aug-19-2020 15:44:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Feb-08-2021 14:38:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Stephen Thomas	Approved	Mar-12-2021 15:37:33 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Feb-08-2021 14:36:44 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Thomas	Approved	Oct-28-2020 14:17:08 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-19-2020 15:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-19-2020 15:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-19-2020 15:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11401156	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-19-2020 15:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1946	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-19-2020 15:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-19-2020 15:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:44:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-19-2020 15:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-19-2020 15:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-19-2020 15:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-19-2020 15:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1.a

Date	Location	User	Value	Reason
Aug-19-2020 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Coronary Artery Bypass Graft Start Date: UNK/UNK/2011 Ongoing: NO End Date: UNK/UNK/2012	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Coronary Artery Bypass Graft	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 15:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: UNK/UNK/2011	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 15:49:31	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	NO End Date: UNK/UNK/2012
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1.b

Date	Location	User	Value	Reason
Aug-19-2020 15:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical Hi Atherosclerotic Cardi story Term ovascular Artery Dise : ase Start Date: UNK/UNK/2011 Ongoing: YES	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 15:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Atherosclerotic Cardiovascular Ar tery Disease	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 15:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: UNK/UNK/2011	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 15:50:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-19-2020 15:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Hypertension Start Date: UNK/UNK/2 010 Ongoing: YES	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 15:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 15:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 15:50:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-19-2020 15:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History T Pacemaker erm: Start Date: UNK/UNK/2 016 Ongoing: YES	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 15:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Pacemaker	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 15:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 15:50:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-19-2020 15:51:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Seasonal Allergy Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 15:51:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:51:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Seasonal Allergy	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 15:51:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 15:51:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Aug-19-2020 15:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Hypercholesterolemia Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 15:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Hypercholesterol	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 15:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 15:51:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-19-2020 15:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Gout Start Date: UNK/UNK/2019 Ongoing: YES	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

1.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 15:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 15:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Gout	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 15:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: UNK/UNK/2019	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 15:51:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Aug-19-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-19-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 234.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-19-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 69.7	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-19-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-19-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 33.9	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

7.a

Date	Location	User	Value	Reason
Aug-19-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 97.8 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-19-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-19-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 97.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-19-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-19-2020 15:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/19/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-19-2020 15:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 231891	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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
Aug-19-2020 15:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 15:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-20-2020 10:00:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-19-2020 16:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 15:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 15:53:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Aug-20-2020 10:00:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG5JP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 10:00:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPG5JP	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-20-2020 10:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG5JR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 10:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPG5JR	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-20-2020 10:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPYZNR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 10:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPYZNR	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

5.d

Date	Location	User	Value	Reason
Aug-20-2020 10:00:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPYZNS	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 10:00:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPYZNS	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-20-2020 10:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPYZNT	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 10:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPYZNT	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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
Aug-19-2020 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-20-2020 10:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-19-2020 16:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/19/2020	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Aug-20-2020 10:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPYZNL	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 10:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPYZNL	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-19-2020 15:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-19-2020 15:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-19-2020 15:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-19-2020 15:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aug/19/2020 12:55	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-19-2020 15:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-19-2020 15:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Aug-19-2020 15:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-19-2020 15:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Aug-19-2020 15:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-19-2020 15:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 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: 11401156

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-09-2020 16:07:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-09-2020 16:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 16:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 97.8 Temperature Unit F : Temperature Loca ORAL CAV tion:: ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-09-2020 16:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-09-2020 16:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 97.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-09-2020 16:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-09-2020 16:08:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-09-2020 16:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-09-2020 16:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-09-2020 16:20:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 16:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 16:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-09-2020 16:20:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPYZ36	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 16:20:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPYZ36	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-09-2020 16:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-09-2020 16:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-09-2020 16:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-09-2020 16:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sep/9/2020 13:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-09-2020 16:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-09-2020 16:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

7. Route:

Date	Location	User	Value	Reason
Sep-09-2020 16:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-09-2020 16:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Sep-09-2020 16:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 15:21:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Oct/7/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

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-07-2020 15:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-07-2020 15:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-08-2020 12:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-08-2020 03:17:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 15:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-07-2020 15:22:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-08-2020 12:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BP8D8D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 12:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BP8D8D	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-08-2020 12:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG5RM	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 12:04:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPG5RM	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 12:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG5RN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 12:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPG5RN	Initial Entry

5.d

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-08-2020 12:04:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BPG5RP	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 12:04:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BPG5RP	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-07-2020 15:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Oct/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-07-2020 15:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-07-2020 15:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30fb\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: 11401156

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-08-2021 16:22:39 (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: 11401156

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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Date	Location	User	Value	Reason
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Aortic Valve Dysfunction	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Oct/1/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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. 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-10-2021 20:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Aortic Valve Dysfunction: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening?	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

			ng?	
			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> pre-existing medical history	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 16:22:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-10-2021 20:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021131934	Initial Entry

090177e196ae30fb\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: 11401156

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: pain at injection site	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Feb/9/2021 09:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO End Date Time: Feb/10/2021 11:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 1	Initial Entry
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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
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-04-2021 13:32:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 08:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-04-2021 08:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	New Information
Mar-01-2021 23:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for " Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log." is missing. Kindly review and update.

9. Is this event related to study treatment:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 15:38:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30fb\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: 11401156

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-11-2021 16:27:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jan/6/2021	Changed Information
Mar-11-2021 16:26:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Feb/6/2021	Changed Information
Feb-08-2021 14:37:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Feb/8/2021	Transcription Error
Feb-08-2021 14:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1140

Subject No: 11401156

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete

Site Name: (1140) SUNY Upstate Medical University

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Mar-11-2021 16:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 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
Feb-08-2021 14:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 14:36:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-08-2021 14:36:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 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

090177e196ae30fb\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: 11401156

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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I. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-11-2021 22:10:27 (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-11-2021 16:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-11-2021 16:04:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry : Jan/12/2021	Changed Information
Mar-02-2021 00:30:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Date treatment unblinded should be after or same REVAX date when reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION. Please verify and update dates as appropriate or else clarify with the comment. Thank you.
Mar-01-2021 14:28:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Date entered matches source

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Feb-23-2021 12:08:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7352572;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.
Feb-08-2021 14:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry : Jan/4/ 2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-08-2021 14:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae30fb\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: 11401156

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-08-2021 14:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Feb/8/2021	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: 11401156

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
Feb-08-2021 14:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/8/2021	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: 11401156

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
Feb-08-2021 14:39:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Feb/8/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-08-2021 14:39:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-08-2021 14:39:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30fb\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: 11401156

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-08-2021 14:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 14:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-09-2021 10:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 14:39:40 (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-08-2021 14:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-09-2021 10:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BRFBY	Initial Entry

090177e196ae30fb\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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 10:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BRFJBY	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-09-2021 10:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BSGRC2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 10:01:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BSGRC2	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-09-2021 10:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BSGRC3	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 10:01:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BSGRC3	Initial Entry

090177e196ae30fb\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: 11401156

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-08-2021 14:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 14:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-09-2021 11:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 14:51:53 (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.
Feb-08-2021 14:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-09-2021 11:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BP8DYG	Initial Entry

090177e196ae30fb\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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-09-2021 11:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BP8DYG	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1140

Subject No: 11401156

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-08-2021 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-08-2021 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-08-2021 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-08-2021 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Feb/8/2021 12:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-08-2021 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-08-2021 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae30fb\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: 11401156

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-08-2021 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-08-2021 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-08-2021 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-08-2021 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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-08-2021 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30fb\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: 11401156

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
Mar-01-2021 15:36:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Mar/1/2021	Initial Entry

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: 11401156

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
Mar-01-2021 15:36:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-01-2021 15:36:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-02-2021 14:37:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-02-2021 04:38:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-01-2021 15:36:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-01-2021 15:36:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/1/2021	Initial Entry

5.a

090177e196ae30fb\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: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-02-2021 14:37:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BRFJHY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 14:37:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BRFJHY	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1140

Subject No: 11401156

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
Mar-01-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-01-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-01-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-01-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Mar/1/2021 11:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-01-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-01-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae30fb\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: 11401156

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
Mar-01-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-01-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-01-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-01-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Mar-01-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30fb\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: 11401156

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
Oct-07-2020 15:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-19-2020 15:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-19-2020 15:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-07-2020 15:22:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/7/2020	Initial Entry
Aug-19-2020 15:53:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Initial Entry
Aug-19-2020 15:45:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Initial Entry

090177e196ae30fb\Final\Final On: 01-Apr-2021 04:21 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1140

Site Name: (1140) SUNY Upstate Medical University

Subject No: 11401156

Subject Initials: ---

Generated By: (b) (4)

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

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-28-2020 13:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry